

THE IMPACT OF FOLLOW-UP TELEPHONE CALLS ON NONADHERENCE AND TREATMENT SATISFACTION IN HYPERTENSIVE PATIENTS

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REG.No.261540204

Under the Guidance of

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I further declare that this work is original and this dissertation has not been submitted previously for the award of any other degree, diploma, associate ship and fellowship or any other similar title. The information furnished in this dissertation is genuine to the best of my knowledge.

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1. INTRODUCTION

Adherence can be defined as the extent to which patients follow the instructions they are given for prescribed treatments. The term, adherence, is intended to be non-judgmental, a statement of fact rather than of blame of the patient, prescriber, or treatment. Adherence is not the same as “concordance”, which includes a consensual agreement about treatment taking established between patient and practitioner. Many reasons exist for non-adherence to medical regimens, including (but not restricted to) problems with the regimen (such as adverse effects), poor instructions, poor provider-patient relationship, poor memory, and patients’ disagreement with the need for treatment or inability to pay for it.

Assessing the evidence concerning reasons for low adherence is beyond the scope of this review; the interested reader is referred to other sources.¹ Low adherence with prescribed treatments is very common. Typical adherence rates for prescribed medications are about 50% with a range from 0% to over 100%.² To the extent that treatment response is related to the dose and schedule of a therapy; non-adherence reduces treatment benefits and can bias assessment of the efficacy of treatments. With increasing numbers of efficacious self-administered treatments, the need is apparent for better understanding and management of non-adherence. In previous reviews, we examined the accuracy of clinical measures of non-adherence, interventions to improve attendance at appointments for needed medical services, and interventions to enhance medication adherence. We found inconsistent evidence of effects on adherence, and even more limited evidence of effects on patient outcomes. The current version of review updates 2005 version (which

included 57 trials) with 21 new studies.³⁻⁵ Ethical standards for adherence research dictate that attempts to increase adherence must be judged by their clinical benefits, not simply their effects on adherence rates. Accordingly, we included only studies in which both adherence and treatment effects were measured.

COMMON FORMS OF MEDICATION NONADHERENCE

The distinction between unintentional and intentional medication adherence is important. At one time or another, most patients make unintentional errors in taking medications, usually because of forgetfulness or misunderstanding of instructions. However, the literature suggests that intentional nonadherence is also a significant problem, particularly among patients with chronic disorders requiring long-term therapy, such as asthma, hypertension, HIV infection, and diabetes.⁶⁻⁸ One of the most common reasons for missing medications is that individuals feel good and decide not to take their medications. Once a patient obtains a medication, the two most common nonadherent behaviours include omitting one or more doses or taking a medication at the wrong time.⁹ Consumption of extra doses is less common.^{10,11}

Comprehension of the prescribed regimen is the first step in successfully complying with the regimen. Studies have reported that one fifth to one half of elderly patients have difficulty in understanding or lack of knowledge about their medication regimen.¹²⁻¹⁴ Patients may confuse the role and use of their medications, particularly with more complicated regimens. For example, patients with moderate to severe asthma are typically prescribed two forms of medication, a daily anti-inflammatory medication and a “use as needed” bronchodilator to administer when they have symptoms. When patients are interviewed about their understanding of these two medications, there are often gaps in their

knowledge about which of these medications is prescribed to treat the symptoms of an asthma attack. A written medication schedule or figure with instructions can often enhance adherence.¹⁵

CORRELATES OF MEDICATION NONADHERENCE

Despite the magnitude and importance of treatment nonadherence, there are relatively few consistent predictors of pharmacological adherence. In a review of potential predictors of patient adherence, Dunbar-Jacobs and colleagues reported that most of the data are unclear and inconclusive.¹⁶ In addition, adherence in one area does not predict adherence in another area. However, correlates of medication adherence can be characterized by five factors: patient characteristics, clinical characteristics, provider characteristics, the social environment and policy. The fifth area, policy, which includes factors such as financial coverage of medication and drug benefits, is not discussed here.¹⁷ Treatment nonadherence tends to increase as the number of medications taken increases, which suggests that nonadherence may be a greater problem for the elderly.

The elder patients are at increased risk of poor medication adherence due to the increased likelihood of multiple medication usage because of worse severity and number of diseases. Less understood is the relationship of medication adherence among children, which often involves parental involvement. Adolescence by itself is not a reason for nonadherence; medication adherence rates are comparable to those of adults.¹⁸ However, treatment adherence in childhood and adolescence is characterized by specific challenges that are related to biological, psychological and social development. For example, changes in physical appearance and increased comparisons of physical attributes with friends heighten awareness of potentially constraining physical and social side effects of

treatment and may lead to questioning the necessity of medical instructions. For instance, 25% of adolescents with diabetes were found to fail to take insulin injections or required blood tests because they did not believe the treatment was necessary.¹⁹ In addition, unlike adults, parental psychological well-being is related to adherence with medical regimens. Increased parental supervision has been quite effective in the improvement of general adherence among adolescents with diabetes.¹⁹ Age of the child, chronicity of illness, and coping skills of the child are related to medication adherence.²⁰ In addition, disintegrated family structure and functioning are associated with poor medication adherence in children and adolescents with chronic disorders.^{21,22}

METHODS TO INCREASE MEDICATION ADHERENCE

More than 50 separate interventions have been studied to identify methods that increase medication adherence with the ultimate goal of achieving higher rates of blood pressure control. Uncertainty remains as to the optimal approach for increasing antihypertensive medication adherence, however. In recent years, several systematic reviews and meta-analyses, which pool results of studies with similar approaches and objectives, have been published summarizing the effectiveness of interventions to improve compliance to medications.²³⁻²⁶ Although many of the trials included in these reviews have been heterogeneous, the results of these reviews are informative and provide direction for clinical practice and future research. Interventions aimed at increasing antihypertensive medication adherence fall into several broad categories: patient educational interventions (e.g., didactic teaching), patient behavioral interventions (e.g., patient motivation, support, reminders, drug packaging, simplification of dosing), complex or combined patient interventions (e.g., behavioral coupled with educational), and provider interventions (e.g., tutorials). In this section, studies that used each of

these approaches to increase antihypertensive medication adherence. Patient educational interventions have used one-on-one techniques, group educational sessions, mailed instructional materials, audio-visual aids and knowledge assessments.

Not overall observed increases in medication adherence for interventions involving patient educational methods as a whole were reported in systematic reviews, although a few individual studies reported statistically significant improvements in adherence among patients receiving an educational intervention.^{24, 25, 27}

In a study of 453 managed care patients with hypertension and a health education program aimed at promoting prescription refill compliance, patients (both new and existing diagnosis) randomized to the experimental group (i.e., health education program) compared with the control group had a significant increase in medication possession ratio (defined as the number of days of medication supply obtained by the patient in the study period; $P = 0.001$). This intervention also employed reminders as a behavioural component, however, and may be considered a combined method approach instead of purely educational.²⁸ Hunt *et al*²⁹ randomized 312 patients with mildly uncontrolled hypertension to receive either a mailed educational intervention or standard of care. After 1 year, the investigators found that patients in the intervention arm compared with the control arm reported significantly higher scores on a hypertension knowledge quiz ($P = 0.019$) and greater satisfaction with their care; however, no significant differences were seen in mean blood pressure or patient reported medication compliance between the two groups.²⁹ In a recent study, a patient-centered discharge interview from a general internal medicine hospital service, the investigators found that patients with a better knowledge of side effects of treatment were less likely to discontinue their medications ($P < 0.01$).³⁰

A large number of trials have used behavioral interventions to encourage patient compliance with antihypertensive medications. These approaches encompass a wide variety of techniques including monetary rewards or gifts, counseling, and drug packaging alterations, and have included one to several of these components. Behavioral methods target the psychological barriers to adherence and have proven to be moderately effective. After pooling data reported that behavioral interventions resulted in significant improvements in indirect measures of antihypertensive medication adherence (i.e., refill and pill counts). More importantly, clinically significant improvements in health outcomes (i.e., blood pressure control) resulted from these interventions.²³ Another systematic review showed a 4% improvement in antihypertensive medication adherence associated with behavioral interventions; however, this was not statistically significant.

Although behavioral interventions have resulted in only modest improvements in antihypertensive medication adherence, there may be an opportunity to couple these interventions with other methods to produce meaningful, sustained increases in medication adherence. Simplification of dosing regimens as an approach to increase medication adherence has been examined in several studies. This approach draws on the principle that adherence relies on patients remembering to take medication rather than an unwillingness to tolerate side effects or a lack of motivation for compliance. Two out of three systematic reviews reported that simplifying dosing regimens results in significant improvements in medication adherence, ranging from 6–20%^{24,26} A third review, which included adherence results calculated from only one study using dosing simplification as an intervention, did not support a benefit in compliance from simplified dosing regimens²⁵ Provider education and interventions involving social supports systems have been less frequently

studied. Both health care professionals and family and support groups may have a significant effect on an individual's success in adhering to prescribed therapies and in controlling blood pressure. In recent reviews, provider education interventions are said to result in substantial increases in patient adherence.^{23,25} In one study, patients in the care of providers who received education were more likely to be compliant with taking 75% or more of their pills compared with patients receiving care from providers who did not receive education (61.2% compared with 32.1%, respectively; $P < 0.005$)³¹ The previous reviews highlighted the need for additional randomized trials with hypertensive patients to assess further the role of provider education in improving adherence. Interventions that employ a combination of methods offer a comprehensive approach to increase antihypertensive medication adherence. Several review articles have synthesized studies that evaluated multifaceted interventions aimed to increase antihypertensive medication adherence compared with usual care.^{23, 24, 27} All of these reviews cite advantages to using a multifaceted approach.

Medication adherence was improved in eight of 18 study interventions that used a multifactorial intervention, with adherence increasing between 5% and 41% when compared with usual care in one systematic review, while another reported significant changes not only in adherence but also in clinical outcomes including blood pressure reduction as a result of interventions with combination strategies.^{24,27} In most cases, further work to understand the effectiveness of the individual components involved in these studies of multiple interventions is necessary to minimize cost and maximize observed benefit to the patient. Elucidation of the best method for increasing medication adherence requires future studies with extended follow-up to account for adherence drop-off, use of intervention and control groups, utilization of valid and reliable methods to measure adherence, evaluation

of individual components of combination interventions, measurement of clinical outcomes (intermediate and long-term) by assessors blinded to the group assignment, and creation of patient-tailored approaches targeting more of the underlying factors influencing individual adherence.

Cost sharing, gaps in drug coverage, and patient adherence to prescribed medications

A potential barrier to medication adherence is the high cost of prescription drugs and lack of or variability in drug benefits.³²⁻³⁴ For Medicare beneficiaries, the new National Medicare Prescription Drug Benefit will provide important coverage for drugs and should help overcome this barrier. Like other drug benefit packages available in healthcare (e.g., managed care organizations), however, there is a proposed annual drug benefit cap, which could lead to a gap in coverage for drugs and subsequently lower adherence when patients exceed this annual cap. Recently, Tseng et al.³⁵ conducted a survey of Medicare + Choice beneficiaries with high medication costs and benefits capped on the plan's share of the drug cost to describe, in part, strategies adopted by beneficiaries exceeding annual drug benefit caps. In multivariate analyses, beneficiaries who exceeded the cap 75–180 days before the end of the year reported more often that they reduced their use of medication when compared with patients who did not exceed the cap (18% compared with 10%, respectively; $P < 0.001$).

The 197 beneficiaries decreasing medication use because of costs resulted in 323 drug-reducing events (i.e., number of times use of a drug was reduced because of cost), with four classes of antihypertensive drugs (diuretics, angiotensin-converting enzyme inhibitors, calcium channel blockers, and β -blockers) ranked in the top 20 of these events. Study

participants who exceeded their Medicare drug benefit cap were more likely than participants who did not exceed their cap to switch medications (15% compared with 9%; $P = 0.002$), use free samples (34% compared with 27%; $P = 0.006$), call pharmacies to find the best price (46% compared with 29%; $P < 0.001$), and obtain discounts for being 65 years or older (12% compared with 7%; $P = 0.003$). The authors encouraged healthcare professionals to explore how they can lessen the impact of drug benefit caps on patients' health and financial burden.³⁵ *Goldman et al.*³⁶ examined pharmacy claims data linked with health plan benefits from 30 employers and 52 health plans to determine the effect a doubling in co-payments for drugs on use of the most common drug classes had on patients with private insurance and the chronically ill beneficiaries aged 18–64 years.

For the antihypertensive drug therapeutic classes (including angiotensin-converting enzyme inhibitors, calcium channel blockers, diuretics, beta-blockers, and angiotensin II receptor blockers), a doubling of co-payments was associated with a significant price responsiveness in that there was a 26% overall reduction in the use of these medications in the entire population. Further analysis of antihypertensive drug use in patients with a diagnosis of hypertension and receiving on-going care revealed a reduction in use of antihypertensive medications of only 10%, whereas their use of all other drugs decreased by 27%.³⁶ This reduction in use could have adverse health consequences and result in increased healthcare utilization. These results suggest that changes in pricing and drug benefit plans may affect patient adherence to drug treatment recommendations.

Patient-centered approach or tailored intervention

In light of the multiple factors that potentially affect patient adherence to prescribed therapies and the fact that no single intervention has emerged as superior to others (despite decades of research in this area), a patient-centered approach that tailors an intervention to overcome patient-specific barriers to medication adherence may be in order.^{36,37} Using a generic, nonpatient-specific approach is ineffective if a single intervention such as education is targeted to a group of patients who already have a good understanding of their disease and its treatments. Additionally, a nonpatient-focused combined intervention approach is inefficient because all patients will receive every intervention whether they need it or not. Both of these approaches could result in unnecessary use of resources and may have little to no effect on adherence rates or clinical outcomes.

A recent qualitative study of medication adherence in 106 adult treated African Americans with hypertension who were followed for at least 1 year in a primary care practice described a taxonomy of barriers to and facilitators of adherence.³⁸ Reported barriers included patient-specific factors (forgetfulness, beliefs, attitudes), medication factors (side effects, costs, quality of pills, dosing frequency, and treatment duration), disease-specific factors (symptoms, manifestation of disease), and logistics (access to medications and clinic appointments and inconvenience). The facilitators of high adherence included use of reminders, increased knowledge about hypertension, good doctor-patient communication, having a medication-taking routine, and having a strong social support system.³⁹ These findings are similar to those previously reported by Haynes *et al.*⁴¹ The challenge of identifying methods for increasing adherence lies in matching the facilitators or interventions with the individual patient's barriers while taking into account patient

perspectives and social and cultural variations in medication-taking behavior.

Chabot et al.,⁴⁰ conducted a 9-month quasi-experimental study of a decision-aid software program integrated into a pharmacy computerized prescription management system that proposed interventions tailored to each category of hypertensive patient participating in the study on the basis of adherence and blood pressure control criteria. In a stratified analysis limited to participants with high income, the group that received a tailored pharmacy program compared with the control group had significantly greater reductions in systolic blood pressure (7.8 mmHg compared with 0.5 mmHg; $P = 0.01$) and an increase in the percentage of patients achieving adequate blood pressure control. No benefit of this intervention was observed in participants with low income.⁴⁰ To implement a patient-centered approach aimed at improving medication adherence, it seems prudent to use a valid and reliable method to measure adherence that will provide feedback regarding barriers to adherence. Although accurate measures of low adherence to prescribed therapies are lacking, directly asking patients and watching for appointment nonadherence and treatment nonresponse can signal a problem. Self-reports can be direct, simple, inexpensive, and although they may be limited by memory, they tend not to be overinflated.⁴¹ The patient-provider encounter has been identified as one of the most critical events necessary for maximizing therapeutic goals. A validated self-reported medication-taking measure has been developed to address behavioral reasons for nonadherence. Once these barriers are assessed, the health care provider can suggest specifically tailored recommendations for encouraging family member supports or to identify cueing behaviours to facilitate adherence to medical recommendations.⁴³

Framework for future directions

With the current levels of adherence to antihypertensive drugs, the full benefits of these medications are not being realized. A need exists for more research to evaluate adherence and the effectiveness of the interventions, including patient-tailored approaches, designed to increase adherence. Despite the work done to date, many questions remain about how best to measure and improve patient adherence. To enhance clinical practice and facilitate patient-provider interactions, models of adherence that simultaneously examine the effects and interactions of social, psychological, and biologic variables on reliable and valid measures of adherence should be developed.⁴² A need exists for interventions that can be effectively and efficiently integrated into routine clinical practice. These interventions must be rigorously evaluated for the ability to improve antihypertensive medication adherence, improve blood pressure control, and reduce cardiovascular events.

Hypertension affects approximately 1 billion persons worldwide and about 65 million people in the United States^{43-45,48} Progress has been made recently in prevention, detection, and treatment of hypertension, yet hypertension remains a major public health challenge⁴⁶⁻⁴⁸ Inadequate control of hypertension contributes to cardiovascular disease and stroke morbidity and mortality. Over the last 50 years or so, there has been a significant amount of research aimed at improving patients' adherence to recommended medical therapies. In 2004, several review articles and meta-analyses summarizing the state of the art with regard to antihypertensive therapy adherence and the methods to improve it have been published.

Although no intervention to improve adherence has emerged as consistently superior to other methods, there is a consensus that future

research should focus on consistent use of valid and reliable measures of adherence, stronger study designs, larger sample sizes, blinded assessment of clinical outcomes, and longer duration of follow-up. It remains incumbent on the physician to consider nonadherence as a factor contributing to poor blood pressure control, to communicate the importance of medication adherence in light of patient-specific barriers (i.e., a tailored approach) with their patients, to consider strategies a priori that might lessen the effect of barriers (such as drug benefit caps) on medication adherence in patients with hypertension, and to engage the patient actively in the selection of strategies to improve adherence.

SPECIFIC TYPES OF MEDICATION ADHERENCE STRATEGIES

Medication adherence-enhancing strategies may be implemented concurrent with the introduction of treatment, later in the course as a remediation measure, or as a technique to maintain adherence. The majority of strategies to influence medication adherence have been directed at correction and include contingency contracting,⁴⁹ social support,^{50,51} and multiple behavioral strategies.⁵² These strategies have proved successful in remediation of medication nonadherence but have not been effective in maintenance. Less attention has been given to the evaluation of strategies that might be effective at maintaining adherence. The maintenance-directed intervention strategies used most consistently have been educational or behavioral in nature. Summaries of educational and behavioural interventions are presented next.

Educational Interventions

Educational interventions include written and/or verbal instructions delivered individually, in a group, or by telephone, as well as the use of audio-visual material. Numerous studies have shown a direct

relationship between medication adherence and the patient understands of the regimen. In a meta-analysis of articles written between 1961 and 1984 on intervention strategies, written interventions, except for patient package inserts, were shown to produce increased knowledge and decreased medication utilization errors. The studies on patient package inserts resulted in an average effect size value near zero for both knowledge and medication utilization errors⁵³ Thus, knowledge alone will not change behavior. Following are a few examples of well-designed educational interventions. *Levy*⁵⁴ reported that an intervention involving asthma education from hospital-based specialist asthma nurses improved adherence and clinical outcomes in asthmatic patients. Self-reported adherence was significantly higher in the intervention group for use of inhaled topical steroids and rescue medication for severe asthmatic attacks. In terms of clinical outcomes, intervention patients had significantly higher peak expiratory flow values and significantly fewer symptoms at 6 months than patients in the control group.

A randomized clinical trial to improve self-management practices in a sample of 267 adults with asthma reported significant improvements in self-reported adherence as measured by the Morisky scale among those randomized to the intervention as opposed to usual care.⁵⁵ Improvements in adherence were documented at 12-month follow-up and whereas visits to emergency department or hospitalization for asthma in the past 12 months decreased, there were no significant differences across groups. The intervention included a skill-oriented workbook and a one-to-one counselling session involving discussing the workbook and adherence-enhancing strategies. Information on the various types of asthma medications, including precautions for using them, and forms were provided to assist users in understanding and adhering to medication schedules.

Literacy

The effectiveness of written education materials is influenced by the reading ability of the target group or individual. Owen and colleagues⁵⁶ reported that the mean readability of 445 patient education materials was at the 10th-grade level. Two populations who are often disadvantaged in terms of benefiting from education interventions are individuals with low literacy skills and the elderly. Approximately 50 million U.S. citizens are undereducated, which may limit their ability to understand medication labels and instructions, organize their thoughts and perceptions about the purpose of their medications, and understand how to administer their medications.⁵⁷

In the National Adult Literacy Study, a cross-sectional study of the U.S. population, the proportion of Americans who read at the lowest reading level ranged from 16% among those 45–54 years old to 26% among those 55–64 years old to 44% among those age 65 and older.⁵⁸ In terms of health-related issues, Williams⁵⁹ found that only 42% of the patients in two public hospitals understood directions for taking medication on an empty stomach, and 26% were unable to understand information regarding when a next appointment was scheduled. Basic skills in reading are particularly important in the health care setting where patient participation in planning and implementing therapeutic regimens is critical for success.

Functional health literacy means being able to read and understand health-related materials such as prescriptions, appointment cards, medicine labels, and directions for home health care.⁶⁰ Besides being prevalent, functional health illiteracy is related to poorer health status,^{61,62} fewer health-promoting behaviours,⁶³ and poorer health knowledge.⁶⁴ It cannot be overemphasized that educational programs

should be based on an appraisal of each individual's needs rather than relying upon the application of a package suitable for all. Providers must establish what is known before offering the patient new knowledge. Providers should aim to build in and develop simple points into more complex ideas. Also concrete examples to support or explain concepts should be provided. This is important that the increased reliance on patient literature to supplement educational sessions because of reduced length of hospital stays and fewer follow-up contacts.

Ways of Presenting Written Information

Written instructions about the medication regimen should be a core part of every interaction with the patient. A series of studies by Morrow and colleagues has focused on effective instruction formats for older patients that are generalizable to all literate patients. Comprehension and recall of medication information is facilitated significantly when medication-taking instructions are clear⁶⁵ and structured in lists rather than paragraphs⁶⁶. The use of picture charts, color-coded medication schedules, and large print may enhance older and functionally illiterate adults' level of understanding.

Combined use of written and verbal instruction may enhance treatment adherence.⁶⁷ Patients' lack of understanding of medications relates to technical words, incomplete written instructions, and lack of knowledge of regimen duration. Return demonstration of information (i.e., how to take pills) is a method to ensure patients understand relevant information. Package inserts are important to individuals for risk-benefit information but often fail to provide benefits of treatment and have little effect on self-reported behaviour.⁶⁸ Research has shown that it is better to provide limited amounts of materials, and these materials should relate to and reinforce what is covered in the visit.⁶⁹

Behavioral Interventions

Behavioral strategies, including self-monitoring, cueing, chaining (associating new behaviors with established ones), positive reinforcement, and patient contracting, have been used to enhance medication adherence. A contingency contract is wherein both providers and patients set forth a treatment goal and the specific obligations of each in attempting to accomplish this goal and a time limit for its achievement. Beyond increasing the likelihood of adherence to medication therapy, contracts offer a written outline of the expected behavior, the involvement of the patient in the decision-making process concerning the regimen and the opportunity to discuss potential problems and solutions with the provider, a formal commitment to the problem from the patient, and rewards that create incentives for adherence goals.

Incentives

As in other areas of human psychology, positive reinforcement in various forms to encourage or improve adherence may be more beneficial than chastising the patient for poor adherence. In a study⁷⁰ of renal transplant patients, provision of free immunosuppressive medications resulted in short-term improvements in adherence, but there was no benefit beyond the first year after transplantation. Use of financial incentives to improve adherence has also been advocated but remains controversial. In a literature review,⁷¹ 10 of 11 studies showed improvements in patient adherence with use of financial incentives, particularly for treatment of infectious diseases like tuberculosis.

Using monetary incentives to improve adherence has been condemned by some as coercion and contrary to the “mutual participation principle” of decision making advocated by some.⁷² Examples of some well-developed

behavioral interventions to improve medication adherence are now discussed. Piette⁷³ evaluated the effect of biweekly automated telephone assessment and self-care education calls with nurse follow-up on the management of diabetes.

Compared with usual care, patients in the intervention group reported fewer problems with medication adherence and more frequent glucose monitoring (both $p = 0.03$). Patients in the intervention group also had lower glycated hemoglobin levels, lower serum glucose levels, and fewer diabetic symptoms than those in the control group. Incomplete adherence is one of several possible causes of uncontrolled hypertension. Yet, nonadherence remains largely unrecognized and is falsely interpreted as treatment resistance, because it is difficult to confirm or exclude objectively.

In a study involving hypertensive patients resistant to a three-drug regimen, the use of electronic monitors resulted in improvement in both systolic and diastolic blood pressure over 2 months as a result of adapting drug therapy. In addition, the overt monitoring of adherence stimulated about one third of previously uncontrolled patients to improve their adherence and achieve blood pressure control.⁷⁴

2. LITERATURE REVIEW

Charitini S et al.,⁷⁵ conducted a study to identify differences between perceived information needs for hypertension and medication to treat it and to explore the information channels used by patients and to test what type of information is more important to adhere to medication. In this a questionnaire study was designed and conducted by telephone in the Centre for the Treatment of Hypertension in Athens, Greece, among 743 individuals. The main variables included perceived information needs, information channels, non-adherence to medication and socio-demographic characteristics. Nonadherence to medication was measured using the Morisky scale. Patients reported feeling better informed about hypertension (90%) than medication to treat it (80%). The doctor remains the dominant information source, while the media and magazines on health issues were reported more frequently than the family and the pharmacist. Feeling well informed about medication for hypertension was a predictor of better adherence. Other determinants of adherence were the use of the internet and the media. The results confirm the importance of patients leaving the consultation feeling well informed about their medication as this improves adherence. They also show that the use of the internet and the media can be beneficial for adherence. Given the restricted time the doctor can usually spend with the patient, it is important to know that more emphasis on the information regarding medication is important.

Susan M et al.,⁷⁶ conducted a study which shows the effect of a brief pharmacist telephone intervention in identifying adherence barriers and improving adherence to ACEI/ARB medications among nonadherent patients with comorbid HTN and DM who are enrolled in a Medicare Advantage plan. In total, 186 hypertensive diabetic patients, nonadherent to ACEIs/ARBs (PDC < 0.8), were included in the study. Of the 186

patients, 87 received the pharmacist phone call intervention. Among these patients, forgetfulness (25.29%) and doctor issues, such as having difficulty scheduling appointments (16.79%), were the most commonly reported barriers. After excluding those who switched from ACEIs/ARBs to another medication, 157 patients were included in the logistic regression model. Of those, 131 had continued using ACEIs/ARBs and were included in the linear regression model. The mean (\pm SD) post-intervention PDC for the intervention group was 0.58 (\pm 0.26) and for the control group 0.29 (\pm 0.17). Intervention was a significant predictor of better adherence in the linear regression model after adjusting all the other baseline covariates ($\beta = 0.3182$, 95% CI = 0.19-0.38, $P < 0.001$). Other covariates were not significantly associated with better adherence. In the logistic regression model (discontinuation: 26 [yes]/131 [no]) for predicting medication discontinuation, patients who received intervention were more likely to continue using ACEIs/ARBs (OR = 3.56, 95% CI = 1.06-11.86), and those with a higher comorbidity index were less likely to continue using them (OR = 0.72, 95% CI = 0.53-0.99). The brief pharmacist telephone intervention resulted in significantly better PDCs during the 6 months following the intervention as well as lower discontinuation rates among a group of nonadherent patients with comorbid HTN and DM. The overall PDC rates in both the intervention and control groups were still lower than the recommended 80%. Improving adherence to clinically meaningful values may require more than a brief pharmacist phone call. Incorporating motivational interviewing techniques with follow-up calls to address adherence barriers may be more influential in forming sustainable behavioral change and enhancing medication adherence.

Kim et al.,⁷⁷ conducted a study to examine predictors of intentional and unintentional nonadherence to antihypertensive medication regimens and their relationships to blood pressure outcomes. A cross-sectional analysis was performed to assess the factors affecting nonadherence to antihypertensive medication regimens. A total of 445 Korean Americans with HBP was enrolled in the trial at baseline. Of these, 208 participants who were on antihypertensive medication were included in the analysis. Using multivariate logistic regression, we examined theoretically selected variables to assess their relationships to intentional and unintentional nonadherence in this sample. The results shows that approximately 53.8% of the subjects endorsed 1 or more types of nonadherent behaviors. After controlling for demographic variables, multivariate analysis revealed that a greater number of side effects from the medication (adjusted odds ratio [OR], 1.19; 95% confidence interval [CI], 1.07 to 1.33) and a lower level of HBP knowledge (adjusted OR, 0.89; 95% CI, 0.79 to 0.99) were significantly associated with intentional nonadherence. Unintentional nonadherence was less strongly associated with the study variables examined in the analysis. The present findings indicate that intentional nonadherence to antihypertensive medication that stems from incomplete knowledge of HBP treatment is prevalent among middle-aged Korean Americans with HBP. The results highlight the strong need for an intervention that focuses on increasing patient knowledge about HBP, including the benefits and side effects of antihypertensive medication. This type of focused intervention may help reduce intentional nonadherence to antihypertensive medications and ultimately result in achieving adequate BP control in this high-risk group.

WoollardJ et al.,⁷⁸conducted a study whichshows that, whether a lifestyle modification programme implemented by nurse counsellors in a general practice setting would improve blood pressure (BP) control in

treated hypertensive patients. Patients were randomized into a control group or one of two intervention groups who received either a high or low level of counselling. Patients in the intervention groups had appointments every 4th week for 18 weeks. The low intervention group had one practice appointment and five telephone counselling appointments while the high intervention group had six appointments in their general practice. The patients were counselled using a stage of change behavioural model and motivational interviewing to: reduce alcohol consumption, dietary fat and salt intake and weight; cease smoking; and increase leisure time physical activity. Compared with controls the low intervention group showed decreases in alcohol and salt intake while the high intervention resulted in significant decreases in both weight and BP. We conclude that nurse counselling targeted to specific aspects of lifestyle can improve BP control and weight in treated hypertensive patients over 18 weeks. Its longer term effectiveness in the management of hypertension warrants further evaluation.

Jennifer YFet al.,⁷⁹ conducted a study to investigate the effects of compliance and periodic telephone counselling by a pharmacist on mortality in patients receiving polypharmacy. 502 of 1011 patients receiving five or more drugs for chronic disease found to be non-compliant at the screening visit were invited for randomisation to either the telephone counselling group (n = 219) or control group (n = 223) at enrolment 12-16 weeks later. Primary outcome was all cause mortality in randomised patients. Associations between compliance and mortality in the entire cohort of 1011 patients were also examined. Patients were defined as compliant with a drug if they took 80-120% of the prescribed daily dose. To calculate compliance score for the whole treatment regimen, the number of drugs that the patient was fully compliant with was divided by the total number of prescribed drugs and expressed as a percentage. Only patients who complied with all recommended drugs

were considered compliant (100% score). The results show that 60 of the 502 eligible patients defaulted and only 442 patients were randomised. After two years, 31 (52%) of the defaulters had died, 38 (17%) of the control group had died, and 25 (11%) of the intervention group had died. After adjustment for confounders, telephone counselling was associated with a 41% reduction in the risk of death (relative risk 0.59, 95% confidence interval 0.35 to 0.97; $P = 0.039$). The number needed to treat to prevent one death at two years was 16. Other predictors included old age, living alone, rate of admission to hospital, compliance score, number of drugs for chronic disease, and non-treatment with lipid lowering drugs at screening visit. In the cohort of 1011 patients, the adjusted relative risk for death was 1.61 (1.05 to 2.48; $P = 0.029$) and 2.87 (1.80 to 2.57; $P < 0.001$) in patients with compliance scores of 34-66% and 0-33%, respectively, compared with those who had a compliance score of 67% or more. They concluded that in patients receiving polypharmacy, poor compliance was associated with increased mortality. Periodic telephone counselling by a pharmacist improved compliance and reduced mortality.

Robert HFet al.,⁸⁰ conducted a study which shows the effect of automated telephone patient monitoring and counselling on patient adherence to antihypertensive medications and on blood pressure control. A randomized controlled trial was conducted in 29 greater Boston communities. The study subjects were 267 patients recruited from community sites who were ≥ 60 years of age, on antihypertensive medication, with a systolic blood pressure (SBP) of ≥ 160 mm Hg and/or a diastolic blood pressure (DBP) of ≥ 90 mm Hg. The study compared subjects who received usual medical care with those who used a computer-controlled telephone system in addition to their usual medical care during a period of 6 months. Weekly, subjects in the telephone group reported self-measured blood pressures, knowledge and adherence to antihypertensive medication regimens, and medication side-effects.

This information was sent to their physicians regularly. The main study outcome measures were change in antihypertensive medication adherence, SBP and DBP during 6 months, satisfaction of patient users, perceived utility for physicians, and cost-effectiveness. The mean age of the study population was 76.0 years; 77% were women; 11% were black. Mean antihypertensive medication adherence improved 17.7% for telephone system users and 11.7% for controls ($P = .03$). Mean DBP decreased 5.2 mm Hg in users compared to 0.8 mm Hg in controls ($P = .02$). Among nonadherent subjects, mean DBP decreased 6.0 mm Hg for telephone users, but increased 2.8 mm Hg for controls ($P = .01$). For telephone system users, mean DBP decreased more if their medication adherence improved ($P = .03$). The majority of telephone system users were satisfied with the system. Most physicians integrated it into their practices. The system was cost-effective, especially for nonadherent patient users. Therefore, weekly use of an automated telephone system improved medication adherence and blood pressure control in hypertension patients. This system can be used to monitor patients with hypertension or with other chronic diseases, and is likely to improve health outcomes and reduce health services utilization and costs.

Bertera E Met al.,⁸¹ conducted a study which shows that the cost-effectiveness of counselling by telephone and by clinic visit contacts were compared in 40 hypertensive patients each of whom received counselling and reinforcement every three weeks for six months regarding diet, exercise, smoking, and coping with stress. Blood pressure declined significantly in both counselling groups (N: 10 each) but not in a control group (N: 20). The cost per patient under control was \$82 for the clinic counselling and \$39 for the telephone counselling strategy, suggesting that telephone counselling was a cost-effective technique.

Miyong TK et al.,⁸² conducted a study which reports the results of a clinical investigation to determine the sustainability of intervention effects to lower blood pressure (BP) that were obtained through a short-term education via home telemonitoring of BP and regular counselling by bilingual nurses during 1 year. A total of 359 middle-aged (40–64 years) Korean immigrants completed a 15-month intervention that consisted of 6-week behavioral education followed by home telemonitoring of BP and bilingual nurse telephone counselling for 12 months. The final analysis revealed a sharp increase in BP control rates sustained for more than 12 months. At baseline, only 30% of the sample achieved BP control (<140/90 mm Hg). After the initial education period (approximately 3 months), 73.3% of the participants had controlled BP levels. The levels of control were maintained and continuously improved during a 12-month follow-up period (83.2%, $P<.001$). These findings suggest that home telemonitoring of BP and tailored counselling are both useful tools to sustain or improve short-term education effects.

Glenys AH et al.,⁸³ conducted a study to examine the measurement of adherence to medication taking in hypertensive patients. Adherence was evaluated primarily by means of MEMS (Medication Event Monitoring System, Aprex Corporation, Fremont, California) an electronic system that records the date and time of opening of the study medication container. Additional measurements such as change in urinary potassium level, capsule count, client self report and physician estimate of adherence were recorded. A randomised clinical trial was used to assign patients to receive the study medication (potassium) or placebo. Descriptive statistics were used to answer the research questions. Frequency and percentage of responses to different measures of adherence were carried out as well as correlation between the measures.

One hundred and seven subjects between the ages of 26 and 80 participated in the clinical trial. The results showed that adherence measures varied with lowest adherence from two items of self-report related to forgetfulness (46 and 55%) and stringent electronic monitoring with the MEMS (58%) to percentages in the 80–90 range for other self-report items and the general adherence scale. Electronic monitoring correlated best with capsule count at visit 5. Implications for health care providers are discussed.

Ana DG et al.,⁸⁴ conducted a study to examine associations of intervention dose with behavior change outcomes in a telephone counseling intervention for physical activity and dietary change. Secondary analysis of intervention participants from a cluster-randomized controlled trial. Primary care practices in a disadvantaged community in Queensland, Australia. Adult patients with type 2 diabetes or hypertension. Patients (n = 228) received telephone counseling over a 12-month period. The initiation phase (1–4 months) consisted of up to 10 weekly or fortnightly calls; the maintenance-enhancement phase (5–12 months) consisted of up to eight monthly calls. Intervention dose was defined as the number of calls completed in total and during each phase and was categorized into tertiles. Diet and physical activity were measured using validated self-report instruments. Multivariate analyses of call completion and change in health behaviors. Those completing a high number of calls were more likely to be female, white, older than 60 years, retired, and earning less than an average weekly Australian wage. Relative to low call completion, high completion during the maintenance-enhancement phase was associated with significantly greater (least squares mean [SE]) behavioral improvement for the following: total fat intake as percentage of calories (–3.58% [.74%]), saturated fat intake (–2.51% [.51%]), fiber intake (4.23 [1.20] g), and moderate-to-vigorous physical activity (187.82 [44.78] minutes). Interventions of longer

duration may be required to influence complex behaviors such as physical activity and fat and fiber intake

Katja A et al.,⁸⁵ conducted a study it shows that hypertension is a common risk factor for stroke/transient ischaemic attack (TIA) and there is good evidence that blood pressure (BP) control prevents recurrent stroke. We investigated whether telephone follow-up (TFU) improved risk factor management in hypertensive patients after stroke/TIA. They conducted a randomised controlled trial and assigned hypertensive patients within 1 month of stroke or TIA to receive usual care ($n = 27$) or usual care plus regular TFU ($n = 29$). Primary outcome was the difference in 12 h ambulatory systolic BP change from baseline to 6 months (Δ SBP) in both groups. TFU at 7 days, 1, 2 and 4 months included patient-focussed education and goal setting. The results shows that the mean baseline BP was 145/83 mm Hg (standard deviation (SD) 21/14). There was no significant difference in Δ SBP over 6 months with TFU. Median Δ SBP was 0 mm Hg (interquartile range 19.5) in the TFU group and 3.0 mm Hg (20) fall in the usual care group ($P = 0.29$). Post hoc analysis showed that statin use increased from baseline to 6 months ($P = 0.02$) and cholesterol was significantly lower at 6 months in all patients (mean reduction 0.95 mmol/l; $P < 0.001$). They concluded that the promoted patient-led management of risk factors did not improve BP control over 6-month follow-up in primary care after stroke/TIA.

Gbenga O et al.,⁸⁶ conducted a study which shows that data is limited on implementation of evidence-based multilevel interventions targeted at BP control in hypertensive African Americans who receive care in low-resource primary care practices. Counselling African Americans to Control Hypertension (CAATCH) is a cluster-randomized clinical trial in which 30 Community Health Centers (CHCs) were randomly assigned to the intervention condition (IC) or usual care (UC). Patients at the IC sites

received patient education, home BP monitoring, and monthly lifestyle counselling, while physicians attended monthly hypertension case rounds, and received feedback on their patients' home BP readings and chart audits. Patients and physicians at the UC sites received printed patient education material and hypertension treatment guidelines respectively. The primary outcome was BP control and secondary outcomes were mean changes in systolic and diastolic BP at 12 months, assessed with an automated BP device. 1059 patients (mean age 56 years; 28% men, 59% obese and 36% with diabetes) were enrolled. The BP control rate was similar in both groups (IC= 49.3% vs. UC=44.5%, OR=1.21; 95% CI, 0.90-1.63; p=0.21). In pre-specified subgroup analyses, the intervention was associated with greater BP control in patients without diabetes (IC=54.0% vs. UC=44.7%, OR=1.45; CI, 1.02-2.06); and small-sized CHCs (IC=51.1% vs. UC=39.6%, OR=1.45; CI, 1.04-2.45). A practice-based multicomponent intervention was no better than usual care in improving BP control among hypertensive African Americans. Future research on implementation of behavioral modification strategies for hypertension control in low-resource settings should focus on the development of more efficient and tailored interventions in this high-risk population.

Deborah SK et al.,⁸⁷ conducted a study to show the poor adherence to treatment recommendations constitutes a major barrier to adequate blood pressure control. Previous reports have identified that over 40% of patients with hypertension do not adhere to medication regimens. Adherence with recommendations depends on many factors and varies from patient to patient and within individual patients. Barriers to adherence include patient, provider, and medication related factors as well as environmental and healthcare system issues. The UMMC Hypertension Clinic is a multidisciplinary clinic providing services for 5000+ persons. Routine care includes careful attention to well recognized

barriers to adherence including patient knowledge and participation, costs, dosage schedules, and adverse effects. Because of this focused multidisciplinary approach to adherence issues, we anticipated adherence in this clinic to exceed usual reported rates. This project was initiated as one arm of a larger study to assess both patient and provider medication adherence practices. In this pilot study, patient reported adherence to medications was assessed using a standardized instrument (Morisky) addressing medication practices, recognition, number and cost. Of the 84 patients completing the questionnaire, only 14% had Morisky scores indicating low adherence. While this is less than ideal, these scores are well above previously reported non-adherence rates for hypertension medications. These clinic rates also reflect adherence for all recommended medications/supplements, not exclusively cardiovascular medications. Non-adherence rates for frequent co-morbid states such as arthritis, diabetes, and hormone replacement therapy usually exceed those for cardiovascular disease. Over 85% of patients reported medium to high adherence. Only 20.7% reported being careless about taking medications, while 36.4% reported that they forget to take medications on occasion. Twenty-five percent reported feeling worse when they miss medications, 18.4% admitted feeling better. Current knowledge of adherence strategies, integrated into a focused multidisciplinary approach, offers enormous promise for decreasing risk and improving patient outcomes. Maximum use of effective strategies with patients, providers, and healthcare organizations and systems can prevent, monitor, and address adherence problems.

Martin CS et al.,⁸⁸ conducted a study to show the adherence to antihypertensive medications represents a crucial success factor for optimal blood pressure (BP) control in clinical practice. This study evaluated whether an additional pharmacist-led medication counselling could achieve better optimal BP control and enhance compliance. In a

designated family clinic in a region with similar resident characteristics to Hong Kong, patients taking \geq one antihypertensive agent with suboptimal compliance were randomly allocated to a brief 3-minute drug advice (control; n = 161) or pharmacist counselling (intervention; n = 113). The two groups were compared by repeated measure ANOVA at 3-months and 6-months with BP control and medication compliance as outcome variables, respectively. The proportions of patients having optimal compliance increased from 0% to 41.1% at 3 months and 61.9% at 6 months ($P < 0.001$). The proportion of patients having optimal BP control improved from 64.1% at baseline to 74.0% at 3 months and 74.5% at 6 months ($P = 0.023$). There were no significant differences between the two groups in the changes of BP control and compliance levels. The study implied that even a brief 3-minute drug advice might lead to improved BP levels among patients on antihypertensive medications in general practice, but did not demonstrate additional effects by pharmacist counseling.

Miyong TK et al.,⁸⁹ conducted a study to determine the sustainability of intervention effects to lower blood pressure (BP) that were obtained through a short term education via home tele-monitoring of BP and regular counselling by bilingual nurses over one year. A total of 359 middle-aged (40–64yrs) Korean immigrants completed a 15-month intervention that consisted of 6-week behavioral education followed by home tele-monitoring of BP and bilingual nurse telephone counselling for 12 months. The final analysis revealed a sharp increase in BP control rates sustained for over 12 months. At baseline, only 30% of the sample achieved BP control ($< 140/90$ mmHg). After the initial education period (approximately 3 months), 73.3% of the participants had controlled BP levels. The levels of control were maintained and continuously improved over a 12 month follow-up period (83.2%, $p < 0.001$). These findings

suggest that BP monitoring and tailored counselling are both useful tools to sustain or improve short term intervention effects.

3. NEED OF THE STUDY

Hypertension is prevalent and remains one of the most significant causes of mortality worldwide. Elevated blood pressure (BP) is a major risk factor for coronary artery disease and its complications like heart failure, stroke, renal insufficiency, and blindness in diabetic patients. The Global Burden of Disease study estimated that hypertension is now the leading risk factor for disability-adjusted life years worldwide. Comprehensive meta-analysis of nonadherence to antihypertensive medication documented a significantly higher proportion (45.2%) of medication nonadherence was noticed among hypertensive patients, particularly uncontrolled BP patients (83.7%).⁹⁰ Adherence to antihypertensive medications is the cornerstone for achieving hypertension control. Hospital discharge can be a time of significant patient dissatisfaction, as patient's transition to a new environment and are expected to understand and recall complex medication and other instruction despite feeling unwell and being under stress. One mechanism that may improve patient satisfaction and clinical outcomes is the use of follow-up telephone calls. Studies shown that telephoning patients after hospitalization for acute myocardial infarction has been shown to increase smoking cessation rates.⁹⁰

4. AIM AND OBJECTIVES OF THE STUDY

AIM

To study the Impact of follow-up telephone calls made by pharmacists to the hypertensive patients on Nonadherence and Treatment Satisfaction.

OBJECTIVES

- To study the demographic details of hypertensive patients
- To analyze the adherence rates of the hypertensive patients.
- To assess the treatment satisfaction of hypertensive patients.
- To improve the treatment satisfaction and medication adherence in the selected non adherent patients by providing telephonic counselling.

5. PLAN OF WORK

Phase I:

- Literature review
- Approval of work from Ethics committee.
- Baseline; Selection of patients and enrolment.
- Obtain consent forms from patients.
- Data collection.

Phase II:

- Assessment of Patients' Medication adherence by using MMAS tool.
- Assessment of Treatment satisfaction by using TSQM tool.

Phase III:

- Patient follow-up for the selected dissatisfied patients, who all are nonadherent.
- Provide counselling by using counselling aids followed by telephonic counselling.
- To provide counselling on various aspects such as, drugs, lifestyle changes, and their disease management, and tell them to inform if any unwanted and unintended effects of drugs occurs at any follow-ups period.
- Data analysis for the factors influencing medication adherence.
- Statistical analysis.

6. METHODOLOGY

The Study was conducted in a Tertiary care Hospital, Erode. A total of 250 patients were selected in the study period of 10 months. The study was based on some inclusion and exclusion criteria as under:

Patient selection

Inclusion criteria:

Patients who met the following criteria were participated in this study:

1. Patients who has been diagnosed with hypertension.
2. Patients 18 years and above of either sex.
3. Those who are on prescribed antihypertensive medications for at least one month.

Patients who agreed to participate need to be explained the nature and the objectives of the study, and take the informed consent forms from the patients.

Exclusion criteria

1. Patients with more than 2 co-morbid diseases.
2. Pregnant/lactating women.

5.2 Sample size: A plan to approach not less than 250 patients.

Material used: Informed consent form, Patient data collection form, Patient Information leaflet (PILS), Treatment Satisfaction Questionnaire for medication (TSQM), Morisky Medication Adherence Scale (MMAS), diary card.

Sources of data

Inpatients: Patient case records, medication charts and lab reports.

Outpatients: Prescriptions.

Data collection:

The data collection tool is a questionnaire, designed-based on an extensive literature review of similar studies. The questionnaire included information regarding patient demographics and clinical characteristics such as: sex, age, education, income, medical history, and co-morbidities. Collect information from the patient about their prescribed medication regimen, including the number of their antihypertensive drugs and other medications.

Adherence assessment can be obtained through the 8-item self-report Morisky Medication Adherence Scale (MMAS). Each item measures a specific medication-taking behavior. Based on Morisky Medication Adherence Scale score the non adherent patients were identified. Non adherent Patients received a follow-up telephone call for the period of 2 months after counselling at the time of consultation. During call, discussed with patients about how they had been feeling, if they had any questions regarding follow-up appointments, if they were able to obtain all their medications, if they understood how to take their medications, if they had experienced any medication-related side effects, and if they had any other questions or concerns. As needed, making the call intervened to correct the medication-related problems and will be notified the inpatient medicine team of patient-reported symptoms or concerns. The telephonic patient education continued every 3 days up to next follow-up visit. To study the impact of pharmacist provided telephonic education

satisfaction surveys were conducted to all patients at the end of the study by using suitable questionnaire.

Questionnaires used in this study

The instrument used in this study consisted of three parts: part one collected socio-demographic, clinical and medication data obtained directly from patients to their medical files; part two was medication adherence test, and the last part was the treatment satisfaction test.

Morisky Medication Adherence Scale (MMAS-8)⁹¹

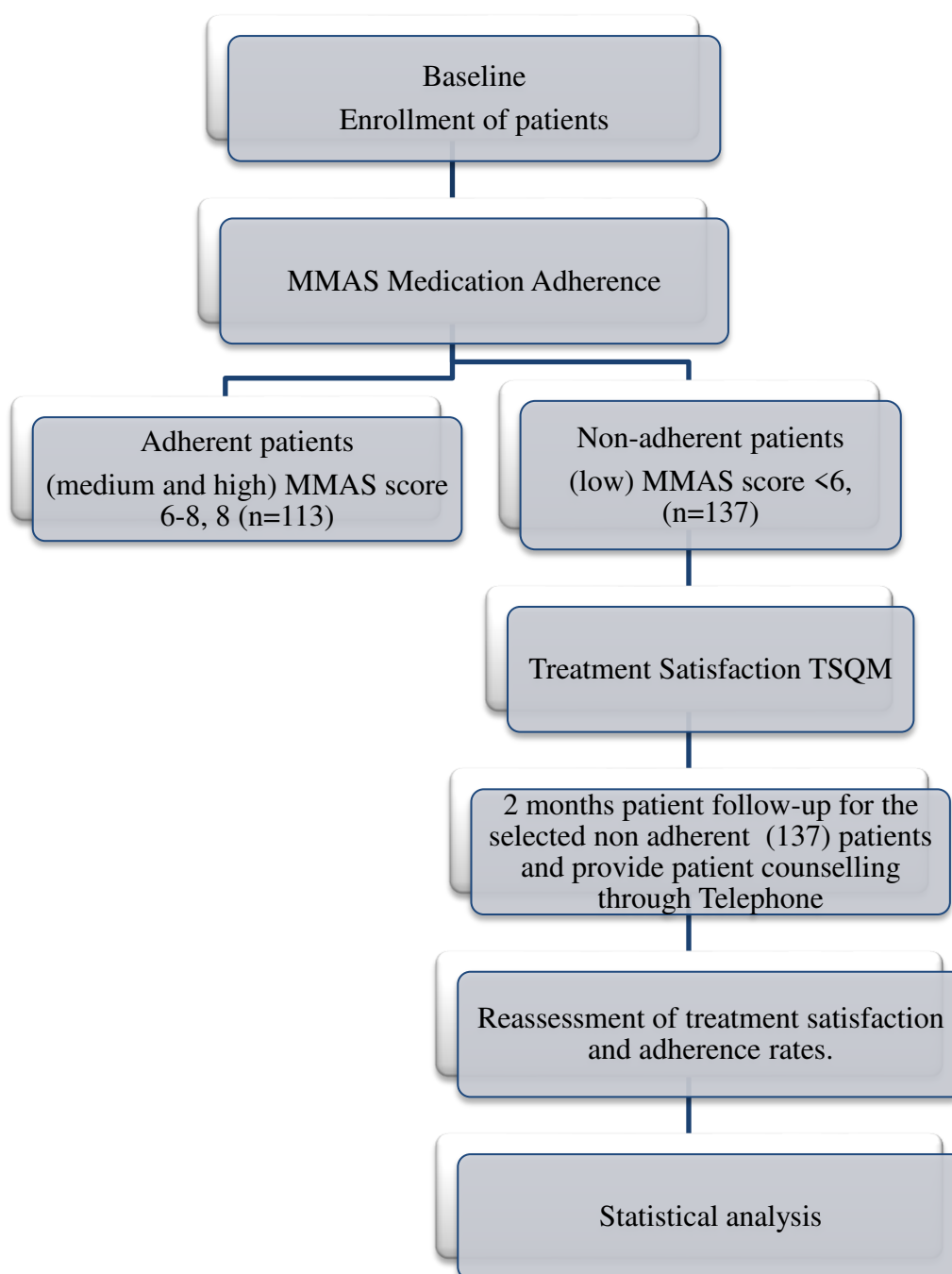
Medication adherence was tested using the validated eight item Morisky Medication Adherence Scale (MMAS-8). MMAS-8 is an 8-item questionnaire with 7 yes/no questions while the last question was a 5-point Likert scale. Based on the scoring system of MMAS, adherence was rated as follows: high adherence (=8), medium adherence (6 to 8) and low adherence (<6). Patients who had a low or a moderate rate of adherence were considered as non-adherent.

Treatment Satisfaction Questionnaire for Medication (TSQM)⁹²

The Treatment Satisfaction Questionnaire for Medication (TSQM) is a widely used generic measure to assess TSQM and has been psychometrically validated in a heterogeneous sample.

The TSQM Version 1.4 is comprised of 14 questions that provide scores on four scales: effectiveness (3 items), side effects (5 items), convenience (3 items) and global satisfaction (3 items).

Figure No: 1 Schematic Representation of Plan of work



7. RESULTS

Table No: 1 Gender wise distribution of hypertensive patients

Gender	Number of patients (n = 250)	Percentage
Male	148	59.2%
Female	102	40.8%

Figure No: 2 Gender wise distribution of hypertensive patients

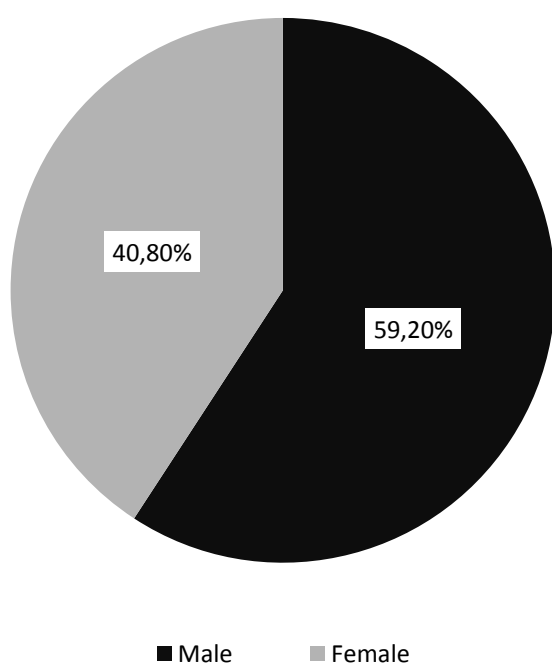


Table No: 2 Age wise distribution of hypertensive patients

Age in years	Number of patients (n = 250)	Percentage
18-44	34	13.6%
45-64	132	52.8%
≥ 65	84	33.6%

Figure No: 3 Age wise distribution of hypertensive patients

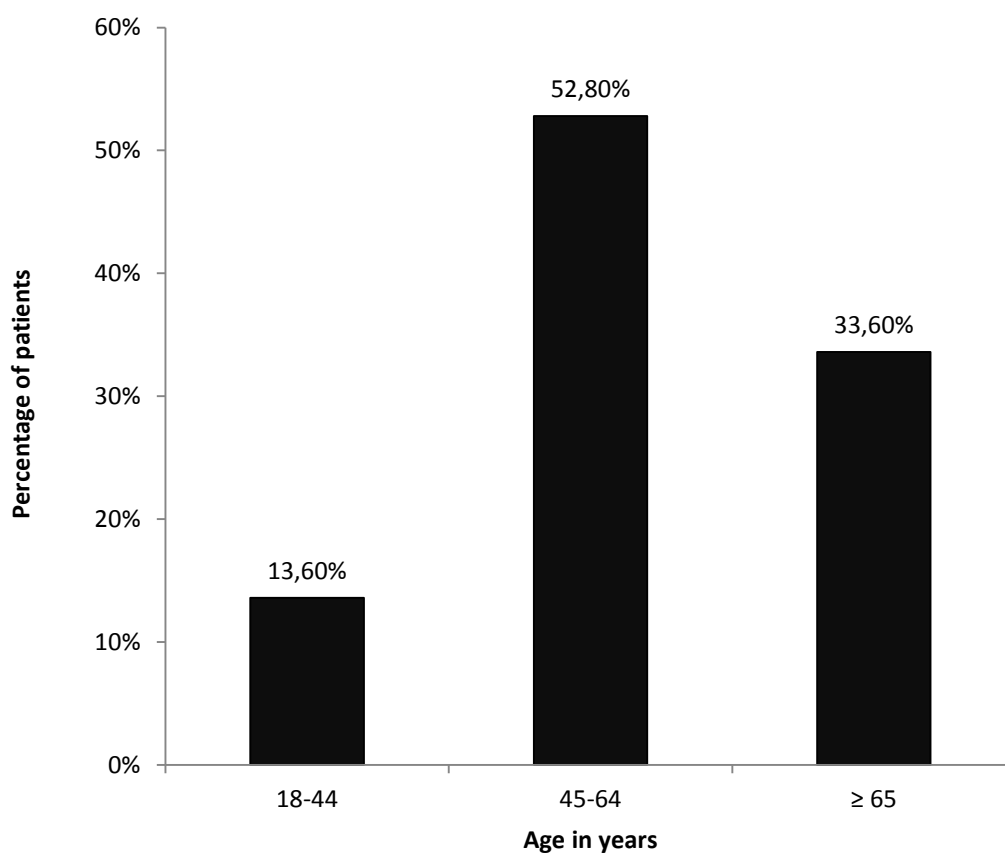


Table No: 3 Hypertensive patients based on Residency

Residency	Number of patients (n = 250)	Percentage
Town	118	47.2%
Village	132	52.8%

Figure No: 4 Hypertensive patients based on Residency

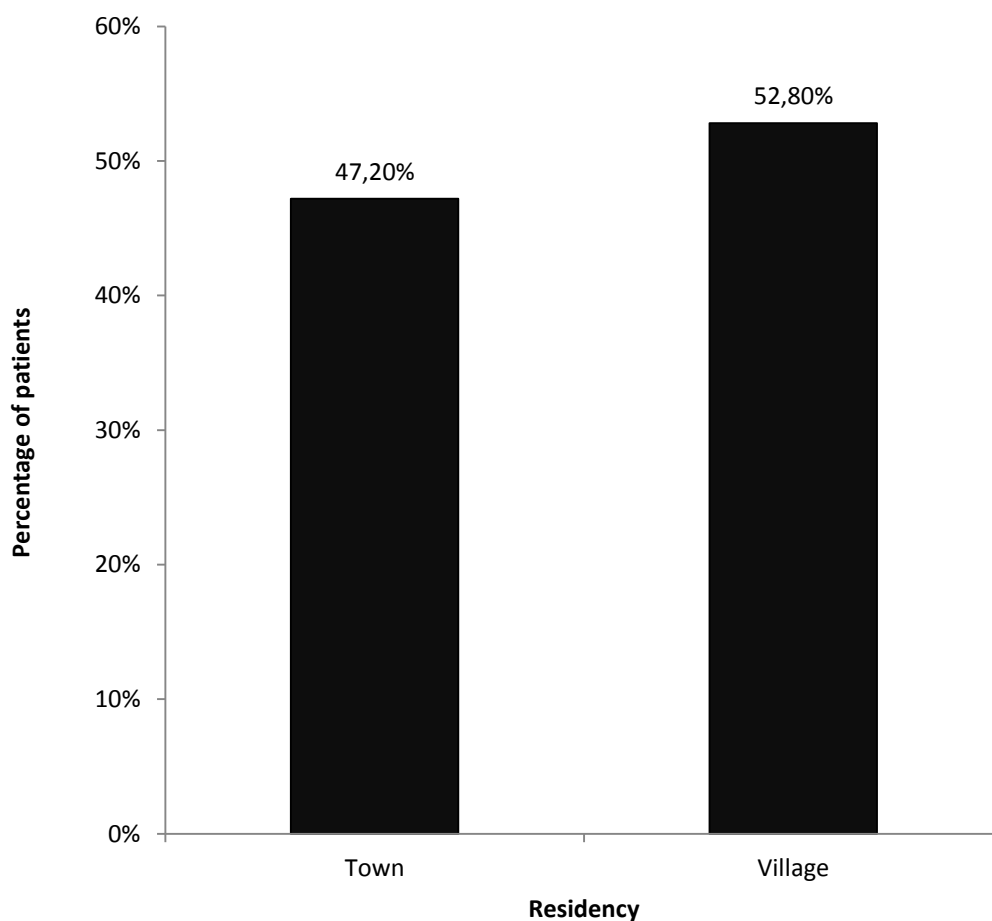


Table No: 4 Hypertensive patients based on Education

Education	Number of patients (n = 250)	Percentage
No formal	17	6.8%
Primary	144	57.4%
Secondary	68	27.2%
Degree	21	8.4%

Figure No: 5 Hypertensive patients based on Education

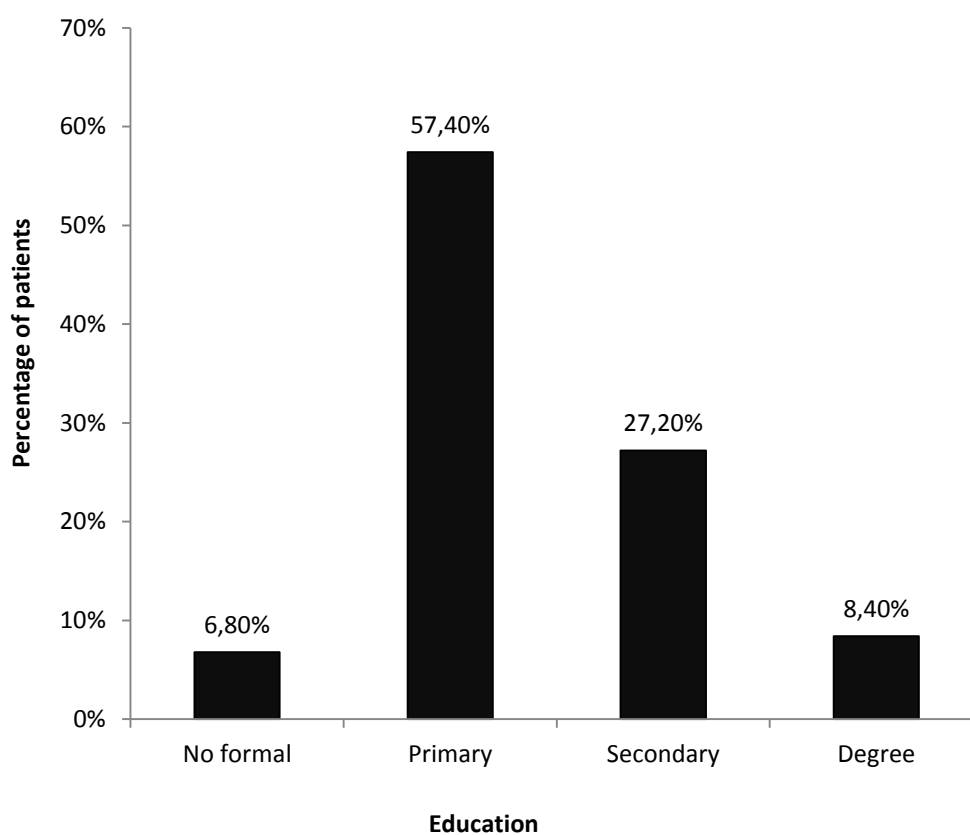


Table No: 5 Hypertensive patients based on Occupation

Occupation	Number of patients (n = 250)	Percentage
Employed	117	46.8%
Unemployed	62	24.8%
Housewife	71	28.4%

Figure No: 6 Hypertensive patients based on Occupation

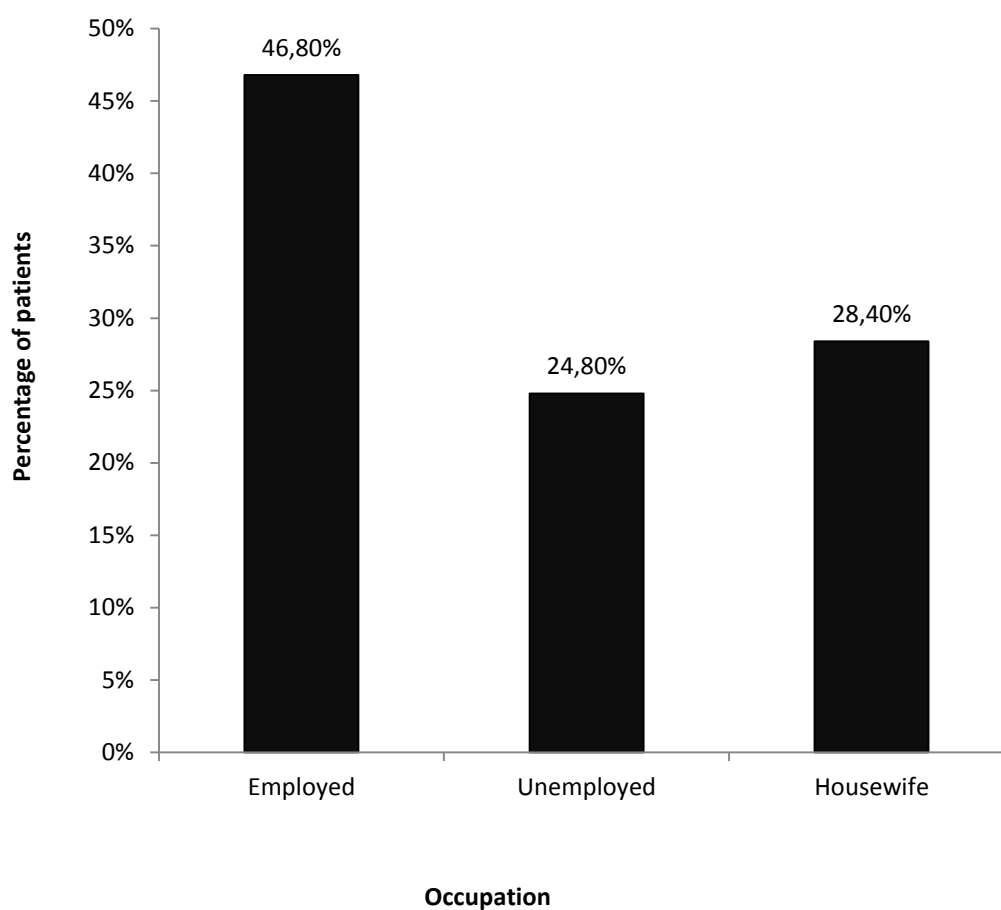


Table No: 6 Marital status among hypertensive patients

Marital status	Number of patients (n = 250)	Percentage
Single/widowed	9	3.6%
Married	241	96.4%

Figure No: 7 Marital status among hypertensive patients

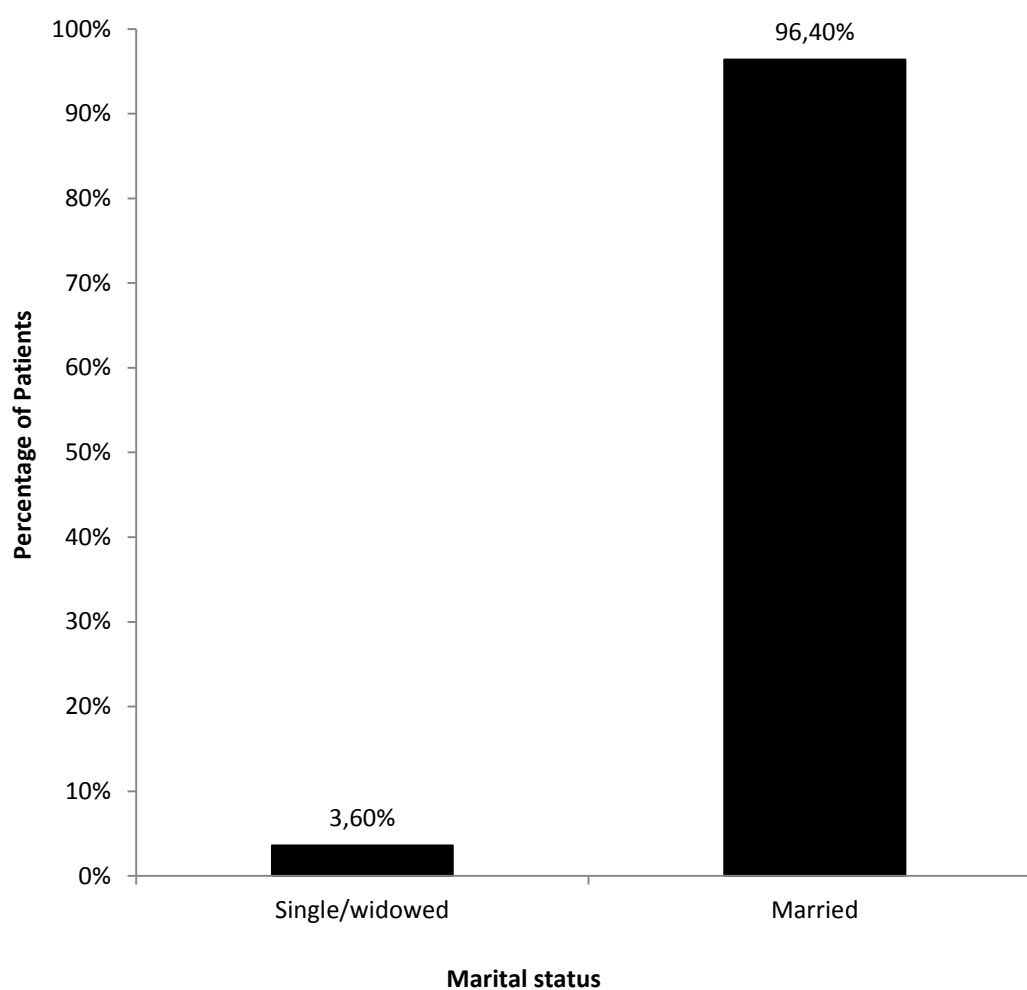


Table No: 7 Hypertensive patients based on their income

Income (Rs)	Number of patients (n = 250)	Percentage
Less than 1000	138	55.2%
1000- 5000	89	35.6%
≥ 5000	23	9.2%

Figure No: 8 Hypertensive patients based on their income

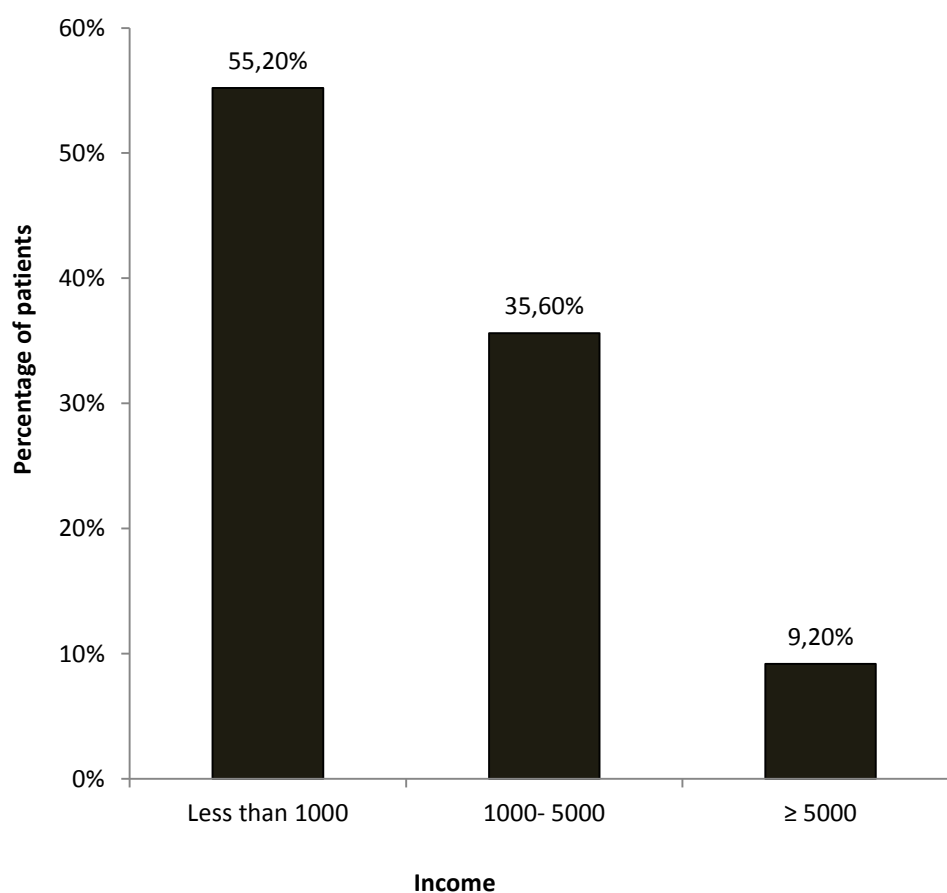


Table No: 8 Duration of disease

Duration of disease	Number of patients (n = 250)	Percentage
< 1 years	49	19.6%
1- 5 years	83	33.2%
≥ 5 years	118	47.2%

Figure No: 9 Duration of disease

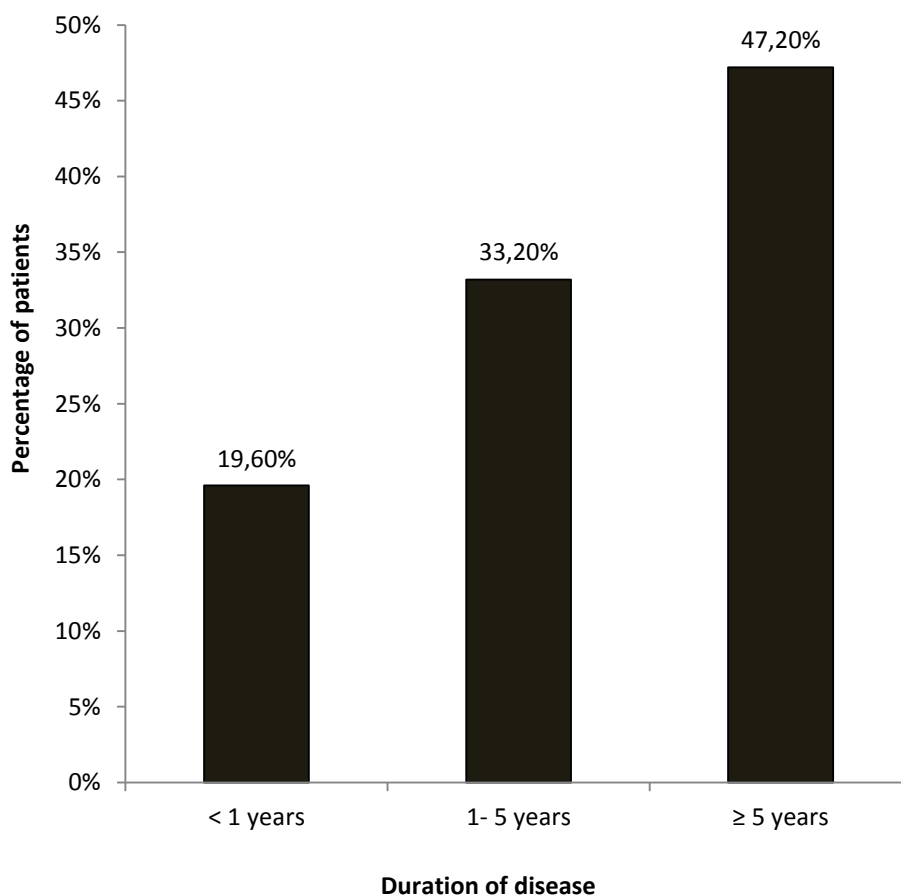


Table No: 9 Hypertensive patients based on their Therapy type

Number of medications per day	Number of patients (n = 250)	Percentage
1 medication	45	18.0%
2 medications	157	62.8%
≥3 medications	48	19.2%

Figure No: 10 Hypertensive patients based on their Therapy type

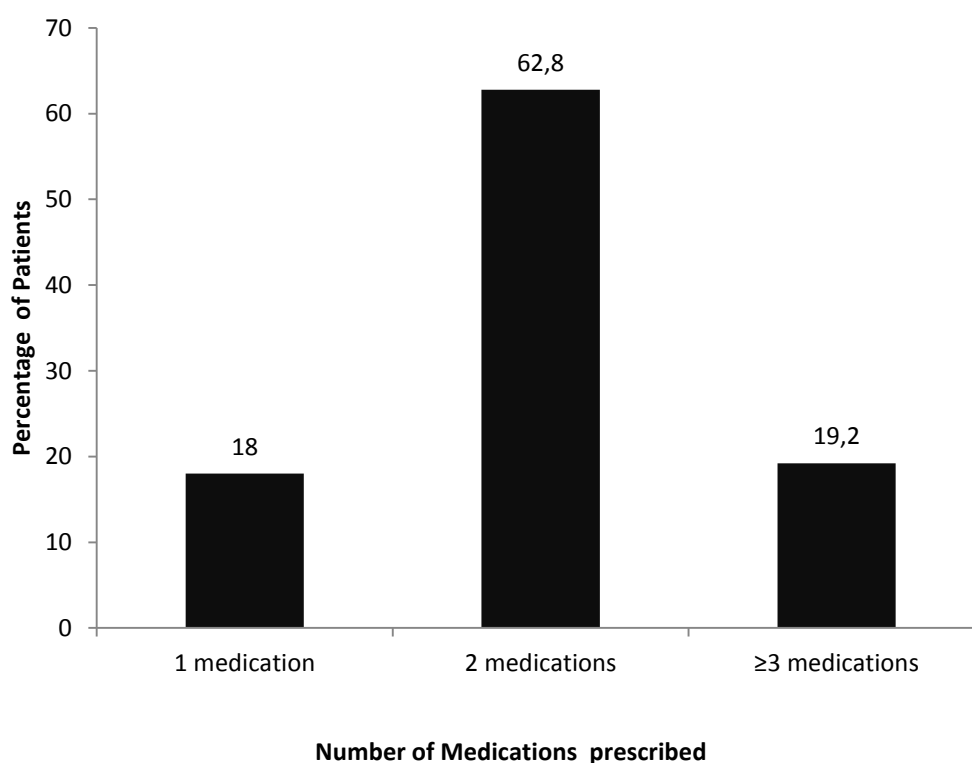


Table No: 10 Hypertensive patients based on presence of other chronic diseases

Presence of other chronic diseases	Number of patients (n = 250)	Percentage
Yes	71	28.4%
No	179	71.6%

Figure No: 11 Hypertensive patients based on presence of other chronic diseases

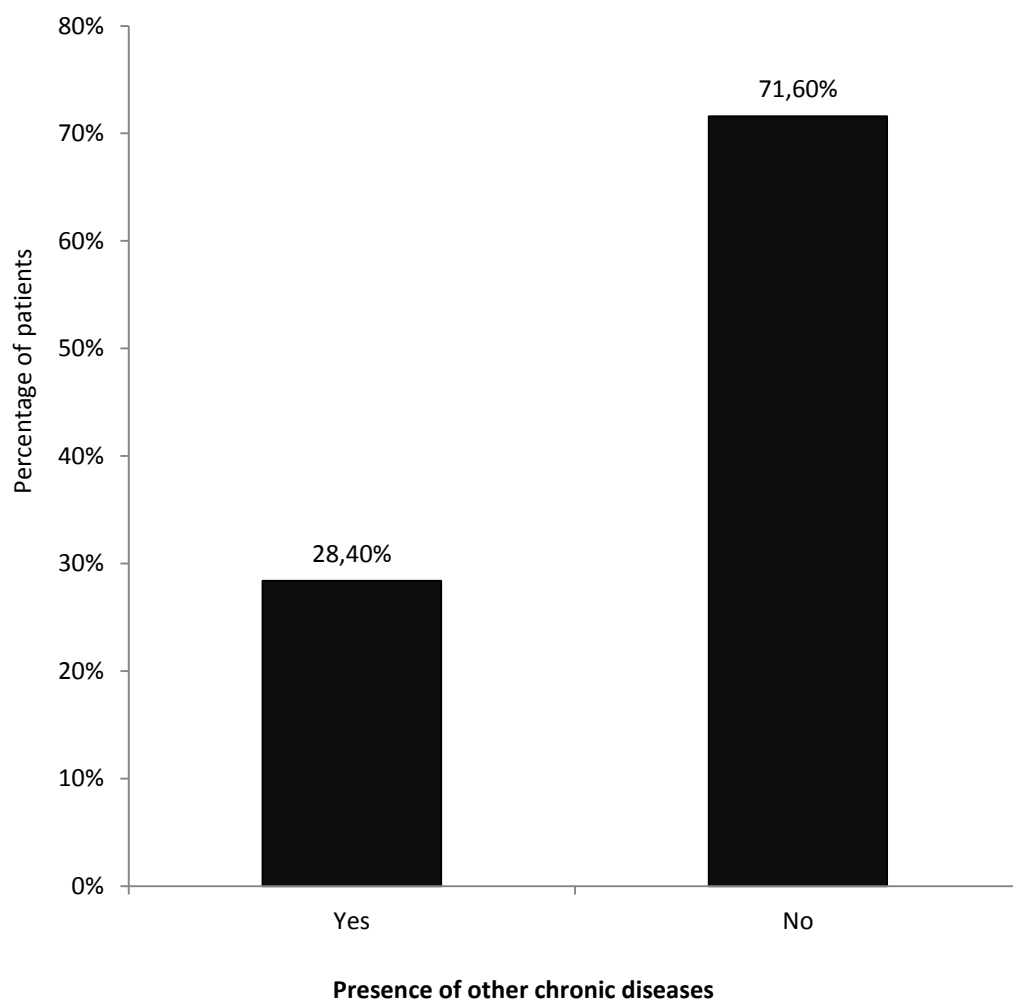


Table No: 11 Socio-Demographics And Clinical Variables with Self-Reported Adherence.

Characteristic	Number of patients (N=250) (%)	MMAS category (score range)	
		Low (< 6) N (%)	Medium/ High (6-8) N (%)
		N=137	N=113
Age in years			
18-44	34 (13.6)	27 (10.8)	8 (3.2)
45-64	132 (52.8)	67 (26.8)	67 (26.8)
≥ 65	84 (33.6)	43 (17.2)	38 (15.2)
Gender			
Male	148 (59.2)	81 (32.4)	71 (28.4)
Female	102 (40.8)	56 (22.4)	42 (16.8)
Residency			
Town	118 (47.8)	59 (23.6)	60 (24.0)
Village	132 (52.8)	78 (31.2)	53 (21.2)
Education			
No formal	17 (6.8)	15 (6)	5 (2.0)
Primary	144 (57.6)	77 (30.8)	65 (26.0)
Secondary	68 (27.2)	38 (15.2)	31 (12.4)
Degree	21 (8.4)	7 (2.8)	12 (4.8)
Occupation			
Employed	117 (46.8)	75 (30)	51 (20.4)
Unemployed	62 (24.8)	22 (8.8)	40 (16.0)
Housewife	71 (28.4)	40 (16.0)	22 (8.8)
Marital status			
Single	9 (3.6)	8 (3.2)	5 (2.0)
Married	241 (96.4)	129 (51.6)	108 (43.2)
Income (Rs)			
Less than 1000	138 (55.2)	89 (35.6)	51 (20.4)
1000- 5000	89 (35.6)	42 (16.8)	45 (18.0)
≥ 5000	23 (9.2)	6 (2.4)	17 (6.8)
Duration of disease			
< 1 years	49 (19.6)	24 (9.6)	27 (10.8)
1- 5 years	83 (33.2)	45 (18.0)	38 (15.2)
≥ 5 years	118 (47.2)	68 (27.2)	48 (19.2)
Presence of other chronic diseases			
YES	71 (28.4)	49 (19.6)	24 (9.6)
NO	179 (71.6)	88 (35.2)	89 (35.6)

Figure No: 12aSocio-Demographics and Clinical Variables with Self-Reported Adherence (age)

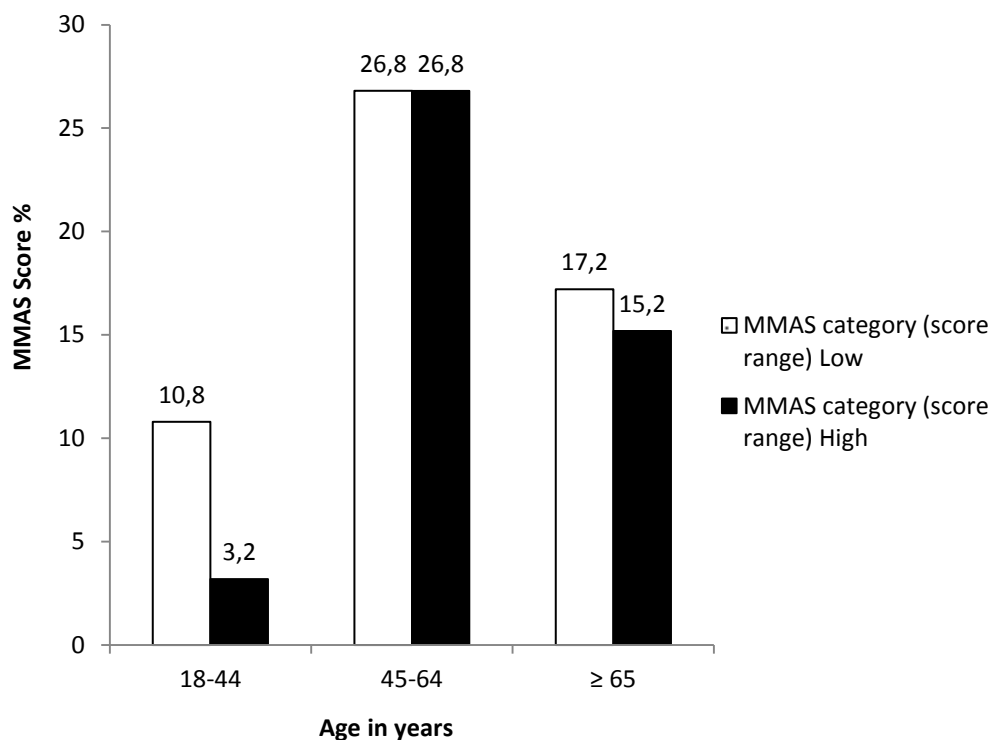


Figure No: 12bSocio-Demographics and Clinical Variables with Self-Reported Adherence (Gender)

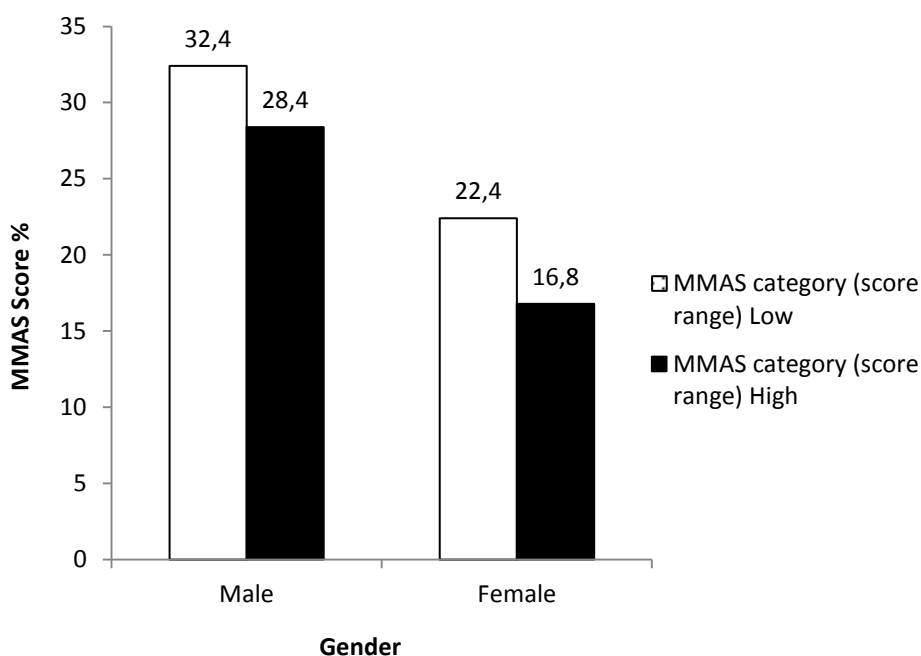


Figure No: 12c Socio-Demographics and Clinical Variables with Self-Reported Adherence (Residence)

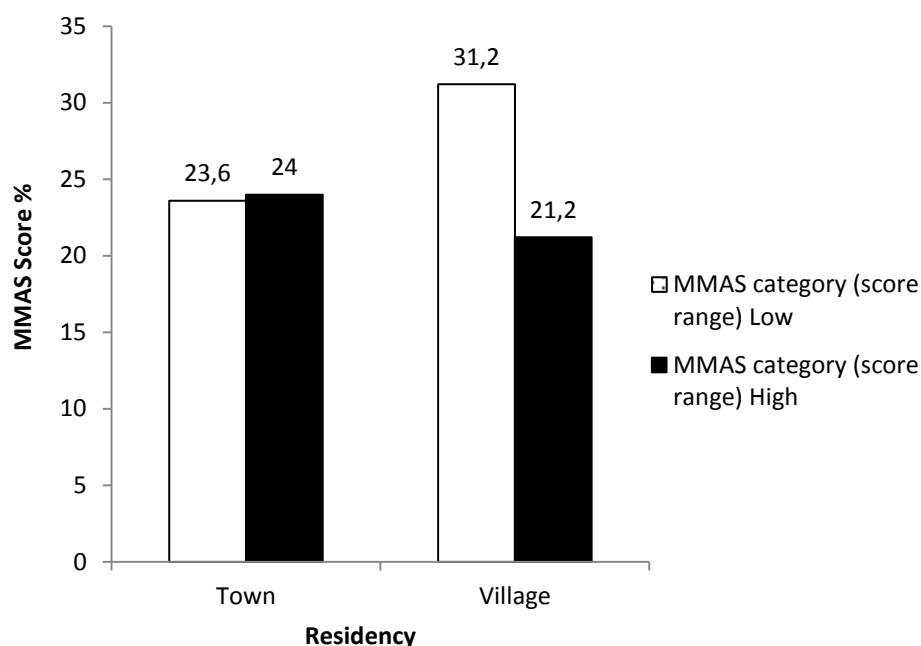


Figure No: 12d Socio-Demographics and Clinical Variables with Self-Reported Adherence (Education)

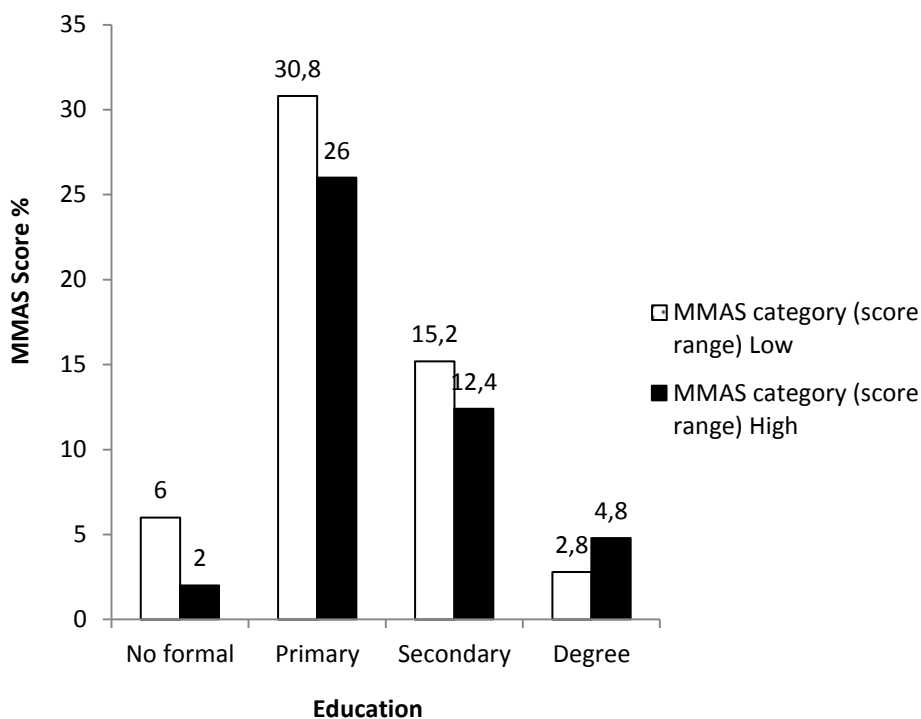


Figure No: 12e Socio-Demographics and Clinical Variables with Self-Reported Adherence(Occupation)

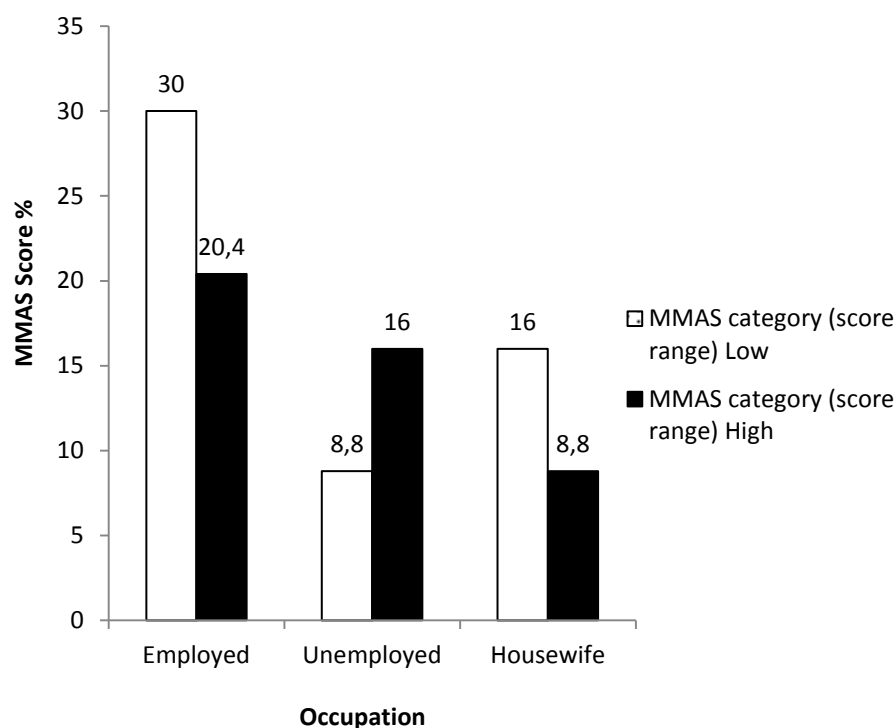


Figure No: 12f Socio-Demographics and Clinical Variables with Self-Reported Adherence (Marital status)

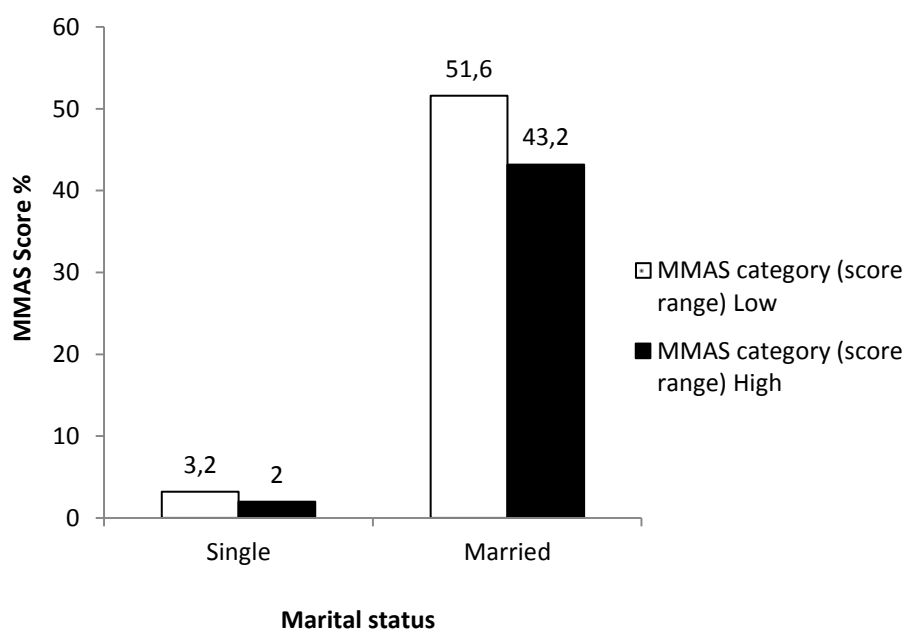


Figure No: 12g Socio-Demographics and Clinical Variables with Self-Reported Adherence (Income)

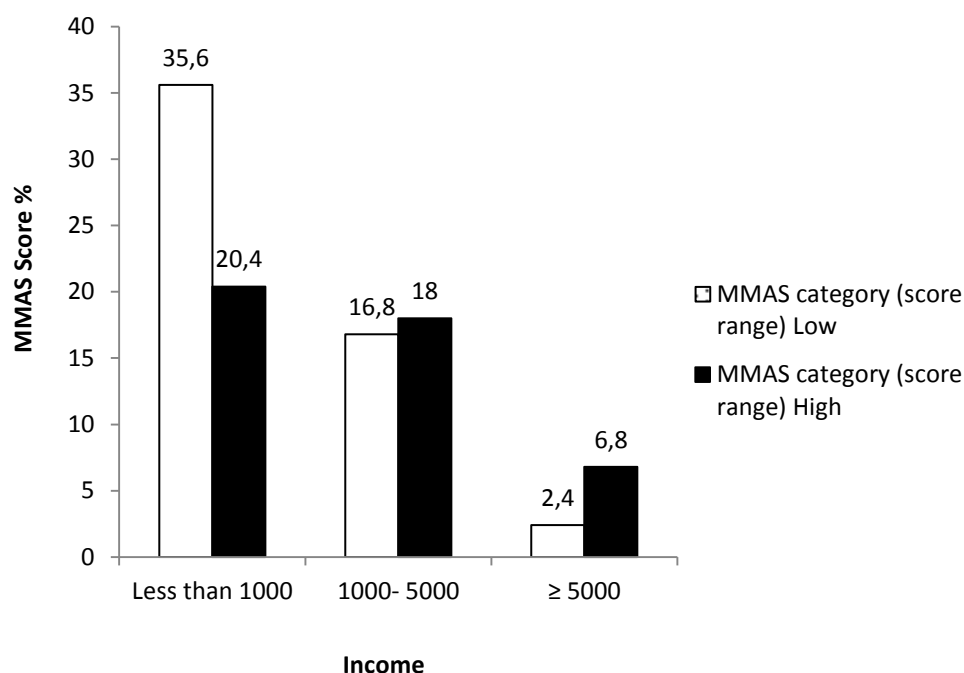


Figure No: 12h Socio-Demographics and Clinical Variables with Self-Reported Adherence (Duration of disease)

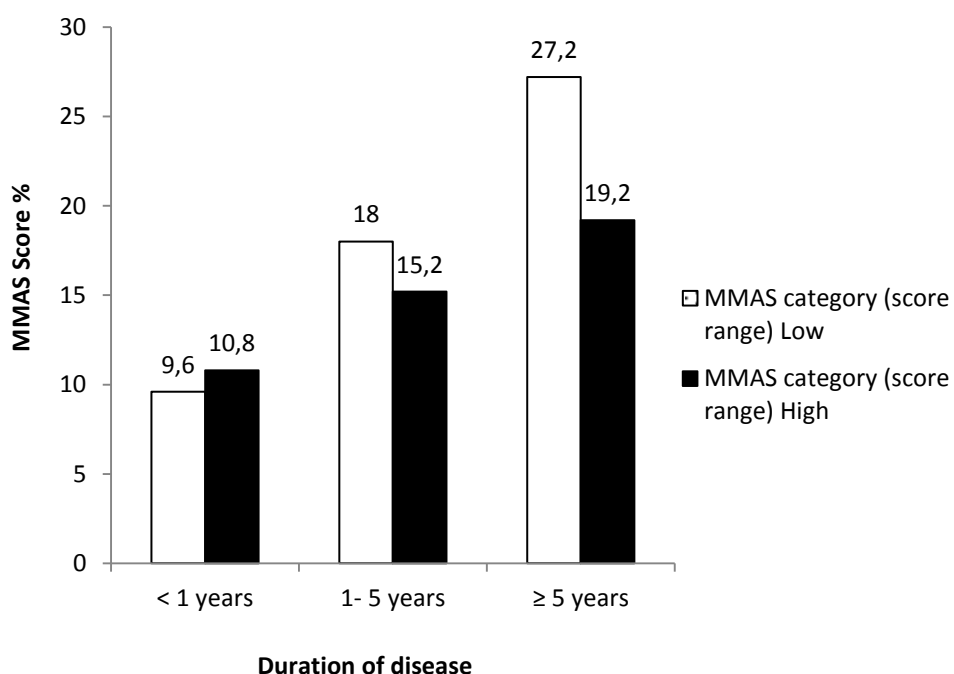


Figure No: 12i Socio-Demographics and Clinical Variables with Self-Reported Adherence. (Presence of other chronic diseases)

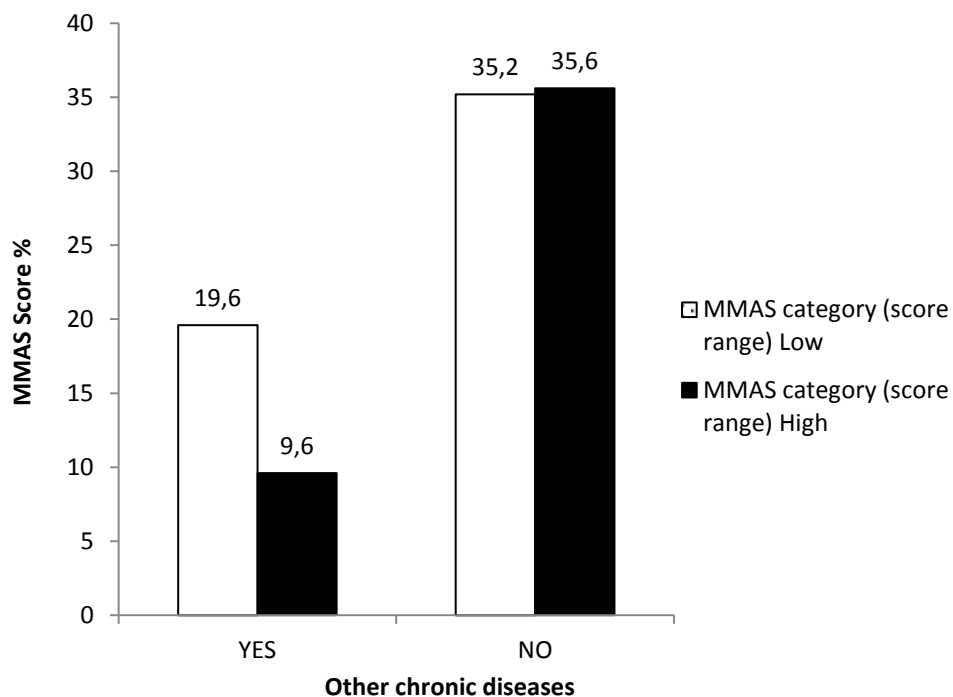


Table No: 12 RESPONSES TO MORISKY SCALE QUESTIONS

MMAS category (score range)	Low (< 6)	Medium/ High (6-8)
Number of patients	137	113
Percentage	54.8 %	45.2%

Figure No: 13 RESPONSES TO MORISKY SCALE QUESTIONS

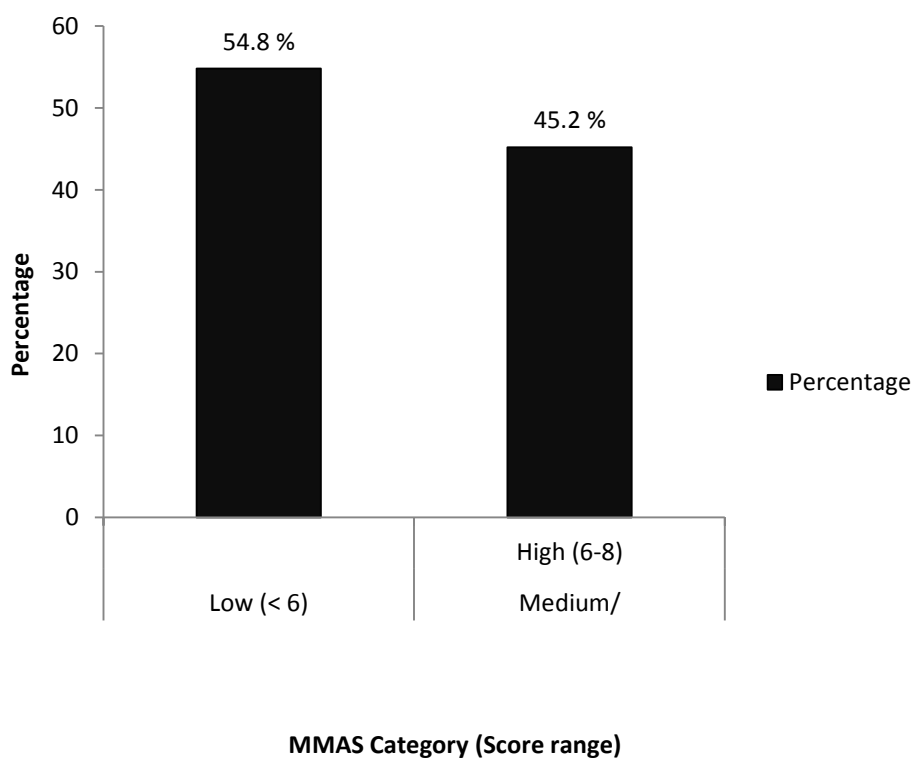


Table No: 13 Treatment Satisfaction TSQM Mean baseline Scores for N = 137

COMPONENTS	MEAN SCORE RANGE (0-100)
Effectiveness	69
Side effects	84
Convenience	46
Global satisfaction	63

Figure No: 14 Treatment Satisfaction TSQM Mean baseline Scores

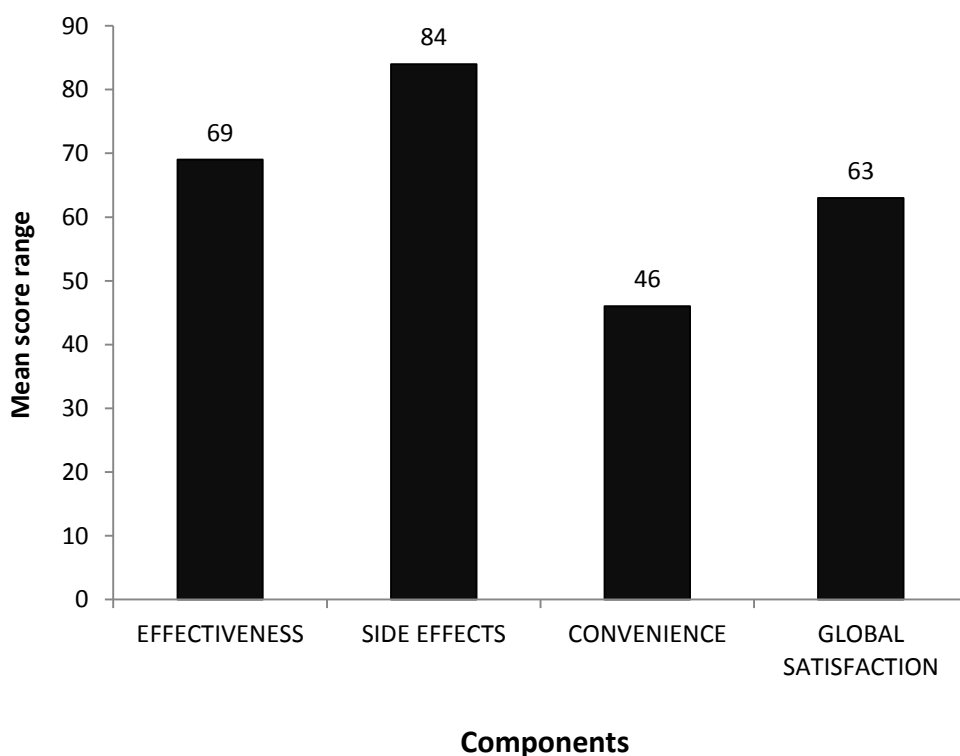


Table No: 14 TSQM Mean Score after 2months of Telephonic counselling(N=137)

TSQM Mean Score (N=137)	Baseline	After 2 months
Effectiveness	69	83
Side Effects	84	84
Convenience	46	85
Global Satisfaction	63	83

Figure No: 15 TSQM Mean Score after 2 months of Telephonic counselling

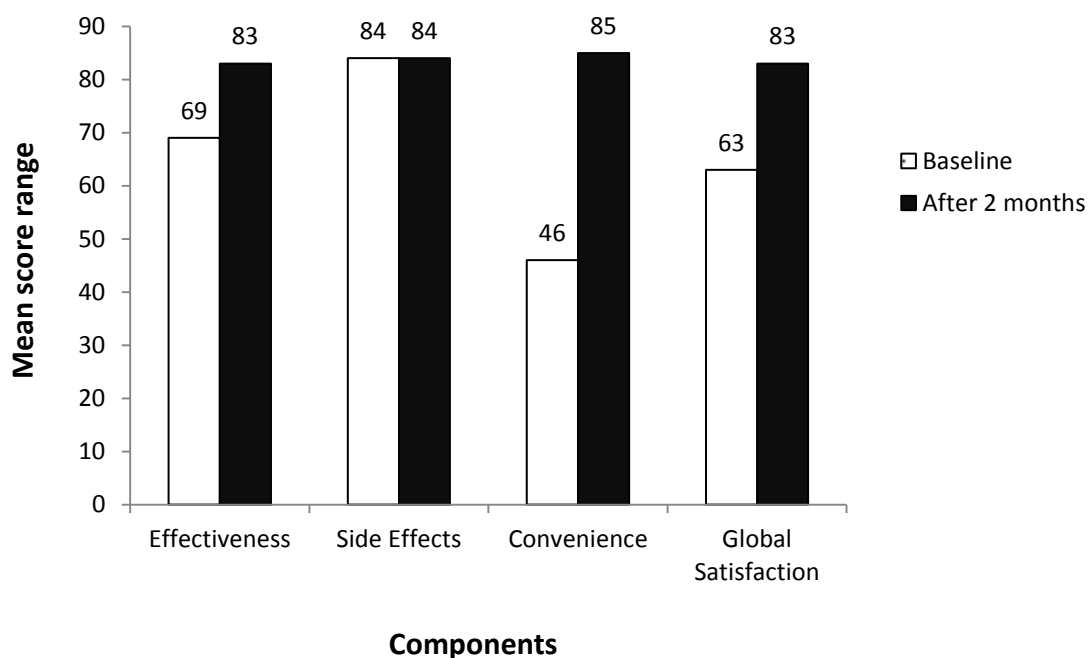


Table No: 15 Changes in Treatment Satisfaction TSQM Mean Scores (N=137)

TSQM Mean Score (N=137)	Baseline	After 2 Months	Absolute change	P value
Effectiveness	69	83	14	0.02
Side Effects	84	84	0	0.91
Convenience	46	85	39	0.02
Global Satisfaction	63	83	20	0.005

Mean difference is significant at P value<0.05

Figure No: 16 Changes in Treatment Satisfaction TSQM Mean Scores

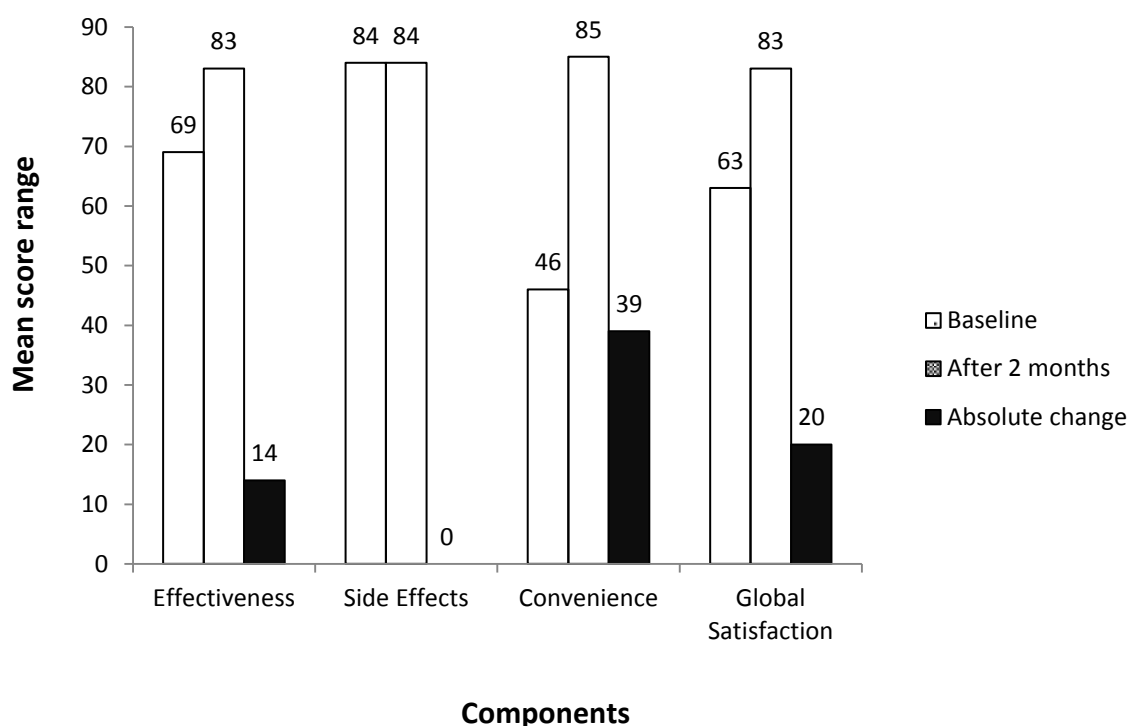


Table No: 16 Changes in Medication Adherence MMAS Mean Scores (N=137)

Medication Adherence	Baseline	After 2 Months	P value
MMAS Mean Score (N=137)	5.1	7.3	0.03

Mean difference is significant at P value<0.05

Figure No: 17 Changes in Medication Adherence MMAS Mean Scores

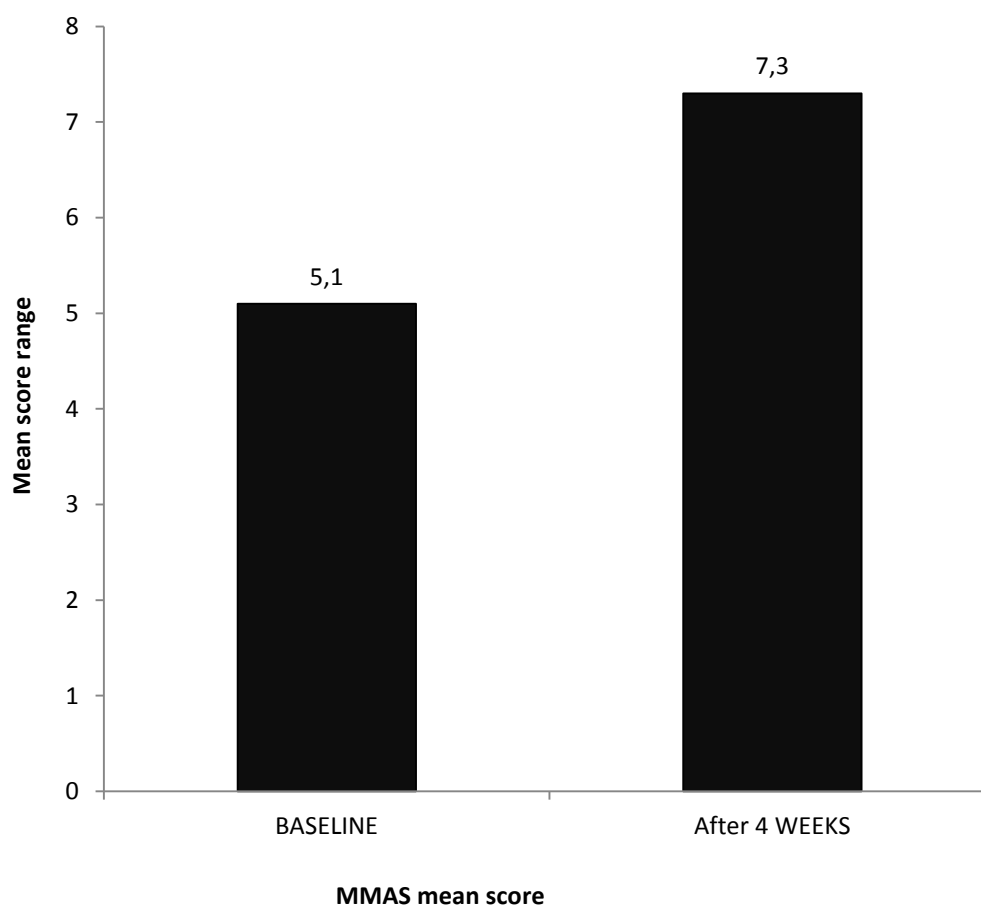


Table No: 17 Impact of 2months telephonic counselling on nonadherence (N=137)

MMAS Score (N=137)	Medium/ High (6-8)	Low (< 6)	P value
Number of Patients	122	15	0.03

Mean difference is significant at P value<0.05

Figure No: 18 Impact of 2months telephonic counselling on non adherence (N=137)

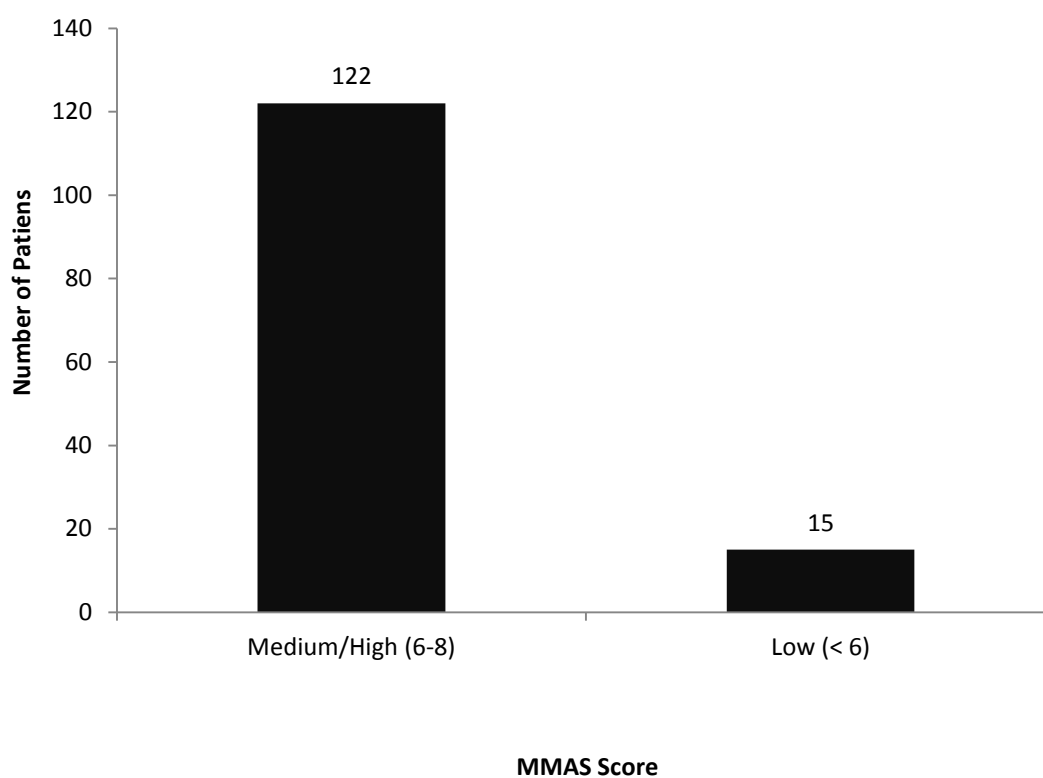
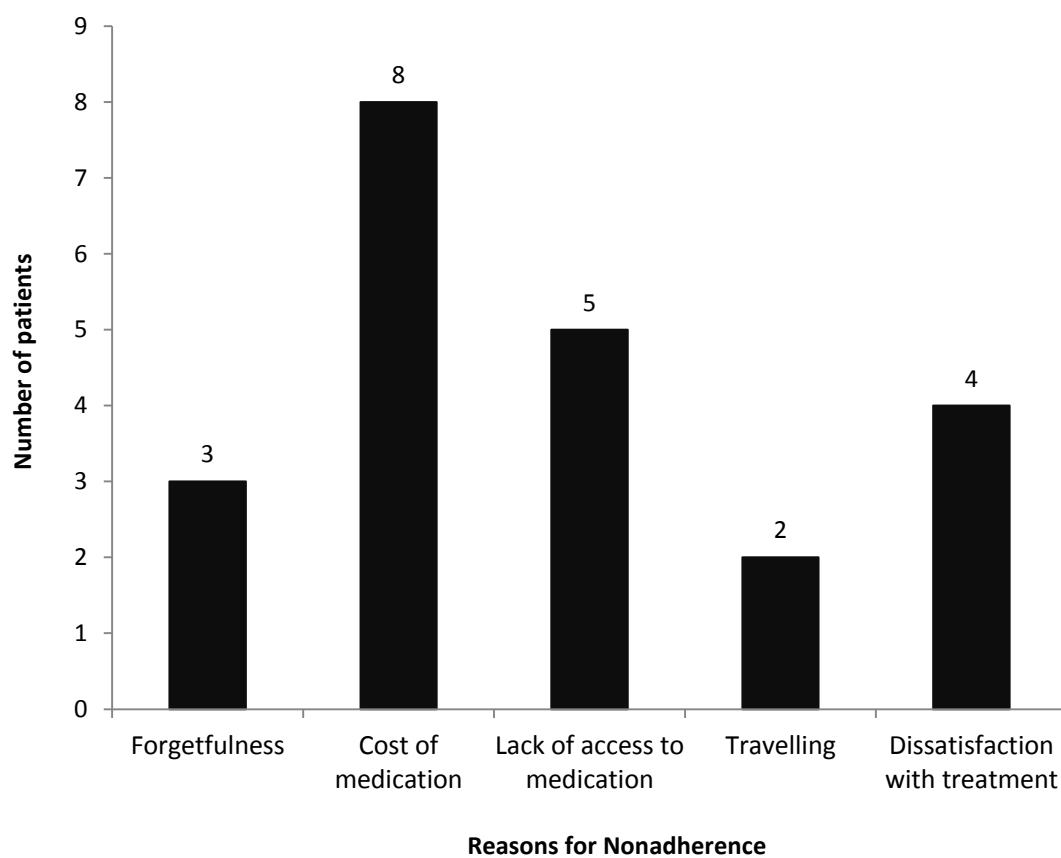


Table No: 18 Reasons for non-adherence to medications after 2 months telephonic counselling. (N=15)

FACTORS	NO OF ANSWERS
Forgetfulness	3
Cost of medication	8
Lack of access to medication	5
Travelling	2
Dissatisfaction with treatment	4

Figure No: 18 Reasons for non-adherence to medications after 2 months telephonic counselling. (N=15)



8. DISCUSSION

The aim of the study is to assess and improve the medication adherence and treatment satisfaction of hypertensive patients by follow-up counselling. A total of 250 hypertensive patients were included in this study. The patients' details were collected using specially designed patient data collection form. In this study, hypertension reporting an age group between 45-64 years is higher (45-64%). This may be the fact that age probably represents accumulation of environmental influences and the effect of genetically programmed senescence in the body systems. Majority of the study population from village for (52.8%) and majority of the patient had primary level of education (57.4%), so there is a positive deviation between education and hypertension. Employed patients (46.7%) significantly associated with hypertension in this reported by Rowaet al.⁹³ Stress can cause hypertension through repeated blood pressure elevations as well as stimulation of nervous system. In the study population 96.4% people were married, 55.2% of the people had low income less than 1000 per month.

In our study, majority (54.8 %) of patients were non-adherent, in that males (59.2%) were found to be low adherent. Study like *Raniah et al*,⁹⁴ proved that adherence was found to be positively correlated with age and duration of illness. In this study younger age between 45-64 years were found to be low adherent. The patients who came from village were found low adherent. Illiteracy was most prominent among the low adherent patients. Patients who had high level of education were adherent 47.2% patients were having hypertension past 5 years or more were found to be low adherent. Also the patients having low adherence due to their

presence of co-morbid disease. It is due to their Living in a village compared to city was a reason for poor adherence this may be also related to lower levels of education, low income and also in addition to reaching doctor.⁹³ Married patients were found adherent when compared to single.

According to MMAS-8, out of 250 patients 137 patients had a low adherence and 113 patients had medium and high adherence rates. According to gender wise category of males were found to be low adherent 81(32.4%) and 71(28.4 %) of males were found to be medium or high adherent. 56 (22.4%) of females patients were found to be low adherent and 42 (16.8%) female patients were found to be high or medium adherent. Patients belongs to village 78 (31.2%) were found to be predominantly non adherent and 53 (21.2%) of villagers showed medium of high adherence rates. Patients who are residing in town 60 (24.0%) seems medium or high adherent and 59 (23.6%) were low adherent. The patient's education status also influences the adherence rates. 12 (4.8%) patients among degree level were found to be medium/high adherent, whereas only 7 (2.8%) were low adherent. There is a positive correlation in case of illiterate and primary level of education as they were found more in number comparatively. Patients who were earning less than Rs 1000 were found to be more non adherent in this category. Living in a village compared with a city was a reason for poor adherence also; this may be related to lower levels of education or income in addition to difficulties in reaching doctors and health-care facilities⁹⁵.

Presence of other chronic disease also influenced the poor adherence rates as 49 (19.6%) patients of this category were found to be low adherent. Evaluating health status as very good, good or poor compared with excellent was significantly associated with poor adherence. In some studies,^{96,97} lower medication adherence was associated with poor health-

related quality of life. Poor health may cause the patient to be depressed and less satisfied with his medications. 28 (81.8%) of Patients who were using more than 3 medications per day were predominantly low adherent, 6 (18.2%) patients of this group were medium/high adherent. This may be due to the burden of remembering more number of drugs and their frequency.

According to TSQM scale findings in the study, the components mean scores for the non adherent patients (N=137) were effectiveness 69, sideeffects 84, convenience 46 and global satisfaction 63. Similar findings were seen in the studies *Zyoudetetal*⁹³ and *Khalaf et al.*⁹⁸

In this study further, the non adherent dissatisfied patients were selected for their improvement of treatment satisfaction and medication adherence by two month patient follow-up counselling. The patients were counselled based on their pharmacological therapy. Regular communication by phone calls and visits was useful for the improvement of patients' satisfaction and medication adherence. Disease and drug information leaflets were printed in local language for improving patients' knowledge.

The TSQM baseline mean scores for 45 patients were recorded as effectiveness 69, side effects 84, convenience 46 and global satisfaction 63. The mean MMAS score was 5.1. After two month patient follow-up there was a significant improvement in their satisfaction domains. Here the significance is based on the p value<0.05, which was calculated using chi square test. The TSQM mean scores after two month were effectiveness 83 (p = 0.02), side effects 84 (p = 0.91), convenience 85 (p = 0.02) and global satisfaction 83 (p = 0.005). There was a significant change in the three satisfaction domains. The MMAS mean score was

recorded as 7.3. Treatment satisfaction domains scores and adherence improved significantly by follow-up telephonic counselling.

After two months telephonic follow-up it was observed that 15 patients had low-adherence to medications. Reasons for low-adherence to medications were analysed as forgetfulness 3, cost 8, and lack of access to medication 5, traveling 2 and dissatisfaction with treatment 4. Similar findings were found in the study done by *Morris et al.*²⁵

Treatment satisfaction may be associated with medication adherence for several reasons, including patients' attitudes or beliefs towards taking antihypertensive medications. *Morisky et al.*⁴¹ and *Bharmal et al.*⁹⁷ stated that the exact mechanism through which treatment satisfaction is associated with medication adherence is unknown; however, low treatment satisfaction appears to be associated with psychosocial well-being which can negatively impact a patient's ability to manage their chronic illnesses and other health problems. Previous studies performed among hypertensive patients have linked treatment satisfaction to numerous factors, which are recognised to be precursors to medication adherence. These include patients' beliefs, their perceived level of competence, knowledge and attitudes about disease treatment, and their overall attitude to life. Further research is needed to understand the real mechanisms through which treatment satisfaction is associated with adherence to antihypertensive medications. The more information and understanding that a patient has regarding a disease and

pharmacological therapies, the more they are likely to adhere to their medications.⁹⁹

9. CONCLUSION

In the current study we found a significant increase in-patient compliance with the recommendations of the physicians after the intervention of the telephone follow-up. In the counseling calls the pharmacists assess and address possible barriers including lack of knowledge, concerns about medication and low necessity beliefs. Our hypothesis is that this type of counseling will improve knowledge, reduce concerns about medication and improve necessity beliefs. This may ultimately improve medication adherence. Although this effect of the intervention on adherence is important, it is as important to assess the impact on the pathway that ultimately leads to adherent behavior. This is because it is this pathway where the pharmacist addresses the needs of each individual patient and where the actual intervention takes place.

The results of this study suggest that counselling through telephone calls provided by pharmacists improves the medication adherence and treatment satisfaction. Pharmacists should find strategies to direct this intervention to patients who are most likely to benefit. Attention should be paid how to reach more patients although the intervention is relatively easy to implement. Patients need information about their medicines for safe and effective use. This includes practical instructions on usage but also information about possible side effects, the expected pharmacological action and what happens if a patient does not take the medication. Physicians and pharmacists play an important role in providing counselling about benefits, risks and correct use of medication. Studies show that information needs of patients are not always met because part of the information is forgotten or remembered incorrectly after consultation. Considering barriers that hamper implementation of

counselling by pharmacies, a counselling by telephone may improve safe and effective use of medications.

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INFORMATION FOR PATIENT

Dear participant,

I **Mrs. HABEEBA RAHMATHULLA CHALILAKATH,**
[REG.No.261540204] student of **J.K.K.Nattraja College of Pharmacy,**
Kumarapalayam currently conducting a project entitled **“The Impact Of
Follow-Up Telephone Calls On Nonadherence And Treatment
Satisfaction In Hypertensive Patients”** for the partial fulfillment for the
award of Degree of **Master of Pharmacy in Pharmacy Practice.**

As the part of project we need to collect data including socio-demographic details, Non adherence, Treatment satisfaction and Medications prescribed from your case sheet.

We will appreciate very much if you could kindly assist us to collect your medical data's. However identifiable personal data's will not be disclosed.

Thank you very much for your kind participation.

CONSENT FORM

I, _____, have read and understand the above information. I have agreed to allow my data to be collected for the project work.

Signature of participant

Date

Signature of translator

ANNEXURE - 1
J.K.K. NATTRAJA COLLEGE OF PHARMACY
KOMARAPALAYAM
DATA ENTRY FORM FOR HYPERTENSIVE PATIENTS

SOCIO-DEMOGRAPHIC DATA

PATIENT NAME:

GENDER: [MALE/ FEMALE]

AGE:

WEIGHT/ HEIGHT/ BMI:

ADDRESS:

PHONE NO:

EDUCATION: PRIMARY/ SECONDARY/ DEGREE

MARITAL STATUS:

OCCUPATION:

INCOME:

TOBACCO USE: YES/NO

DIET: VEG/NON-VEG

ALCOHOL CONSUMPTION: YES/NO

PHYSICAL ACTIVITY: YES/NO

DISEASE RELATED

BP:

PULSE RATE:

DURATION OF THE DISEASE:

TYPE OF THERAPY: MONO/ MULTI

TREATMENT CHART:

S.NO.	MEDICATIONS	FREQUENCY	ROUTE	DATE

ANNEXURE - 2

MORISKY 8-ITEM MEDICATION ADHERENCE SCALE

Number	Question	YES/NO Score Y=0 N=1
1	Do you sometimes forget to take your high blood pressure pills?	
2	Over the past 2 weeks, were there any days when you did not take your high blood pressure medicine?	
3	Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	
4	When you travel or leave home, do you sometimes forget to bring along your medications?	
5	Did you take your high blood pressure medicine yesterday?	
6	When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?	
7	Do you ever feel hassled about sticking to your blood pressure treatment plan?	
8	How often do you have difficulty remembering to take all your blood pressure medication? A. Never/Rarely B. Once in a while C. Sometimes D. Usually E. All the time	

Annexure-3

TSQM (Version 1.4)

Treatment Satisfaction Questionnaire for Medication

Instructions: Please take some time to think about your level of satisfaction or dissatisfaction with the medication you are taking in the clinical trial. We are interested in your evaluation of the effectiveness, side effects, and convenience of the medication over the last two to three weeks, or since you last used it. For each question, please place a single check mark next to the response that most closely corresponds to your own experience.

1. How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?

- ☐ 1 Extremely Dissatisfied
☐ 2 Very Dissatisfied
☐ 3 Dissatisfied
☐ 4 Somewhat Satisfied
☐ 5 Satisfied
☐ 6 Very Satisfied
☐ 7 Extremely Satisfied

2. How satisfied or dissatisfied are you with the way the medication relieves your symptoms?

- ☐ 1 Extremely Dissatisfied
☐ 2 Very Dissatisfied
☐ 3 Dissatisfied
☐ 4 Somewhat Satisfied
☐ 5 Satisfied
☐ 6 Very Satisfied
☐ 7 Extremely Satisfied

3. How satisfied or dissatisfied are you with the amount of time the medication takes to start working?

- ☐ 1 Extremely Dissatisfied
☐ 2 Very Dissatisfied
☐ 3 Dissatisfied
☐ 4 Somewhat Satisfied
☐ 5 Satisfied
☐ 6 Very Satisfied

☐ 7 Extremely Satisfied

4. As a result of taking this medication, do you experience any side effects at all?

☐ Yes

☐ No (if No, then please skip to Question 9)

5. How bothersome are the side effects of the medication you take to treat your condition?

☐ 1 Extremely Bothersome

☐ 2 Very Bothersome

☐ 3 Somewhat Bothersome

☐ 4 A Little Bothersome

☐ 5 Not at All Bothersome

6. To what extent do the side effects interfere with your physical health and ability to function
(i.e., strength, energy levels etc.)?

☐ 1 A Great Deal

☐ 2 Quite a Bit

☐ 3 Somewhat

☐ 4 Minimally

☐ 5 Not at All

7. To what extent do the side effects interfere with your mental function
(i.e., ability to think clearly, stay awake etc.)?

☐ 1 A Great Deal

☐ 2 Quite a Bit

☐ 3 Somewhat

☐ 4 Minimally

☐ 5 Not at All

8. To what degree have medication side effects affected your overall satisfaction with the medication?

☐ 1 A Great Deal

☐ 2 Quite a Bit

☐ 3 Somewhat

☐ 4 Minimally

☐ 5 Not at All

9. How easy or difficult is it to use the medication in its current form?

☐ 1 Extremely Difficult

☐ 2 Very Difficult

☐ 3 Difficult

☐ 4 Somewhat Difficult

- ☐ 5 Easy
- ☐ 6 Very Easy
- ☐ 7 Extremely Easy

10. How easy or difficult is it to plan when you will use the medication each time?

- ☐ 1 Extremely Difficult
- ☐ 2 Very Difficult
- ☐ 3 Difficult
- ☐ 4 Somewhat Difficult
- ☐ 5 Easy
- ☐ 6 Very Easy
- ☐ 7 Extremely Easy

11. How convenient or inconvenient is it to take the medication as instructed?

- ☐ 1 Extremely Inconvenient
- ☐ 2 Very Inconvenient
- ☐ 3 Inconvenient
- ☐ 4 Somewhat Convenient
- ☐ 5 Convenient
- ☐ 6 Very Convenient
- ☐ 7 Extremely Convenient

12. Overall, how confident are you that taking this medication is a good thing for you?

- ☐ 1 Not at All Confident
- ☐ 2 A Little Confident
- ☐ 3 Somewhat Confident
- ☐ 4 Very Confident
- ☐ 5 Extremely Confident

13. How certain are you that the good things about your medication outweigh the bad things?

- ☐ 1 Not at All Certain
- ☐ 2 A Little Certain
- ☐ 3 Somewhat Certain
- ☐ 4 Very Certain
- ☐ 5 Extremely Certain

14. Taking all things into account, how satisfied or dissatisfied are you with this medication?

- ☐ 1 Extremely Dissatisfied
- ☐ 2 Very Dissatisfied
- ☐ 3 Dissatisfied
- ☐ 4 Somewhat Satisfied
- ☐ 5 Satisfied
- ☐ 6 Very Satisfied
- ☐ 7 Extremely Satisfied

ANNEXURE – 4

J.K.K. NATTRAJA COLLEGE OF PHARMACY

KOMARAPALAYAM

DATA ENTRY FORM FOR HYPERTENSIVE PATIENTS

SOCIO-DEMOGRAPHIC DATA

PATIENT NAME:

GENDER: [MALE/ FEMALE]

AGE:

WEIGHT/ HEIGHT/ BMI:

ADDRESS:

Reason for Nonadherence

Forgetfulness	
Cost of medication	
Lack of access to medication	
Travelling	
Dissatisfaction with treatment	